



Exploring the acceptability and effectiveness of psychosocial interventions for stroke patients experiencing depression

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Doctorate in Clinical Psychology

The University of Edinburgh

2014

Acknowledgements

Firstly, I would like to thank all the individuals who participated in this research, without them this would not have been possible. I hope that the findings of this research portfolio will inform future psychological interventions for post-stroke patients experiencing low mood. Thank you to the Stroke Liaison Nurses for their help identifying participants.

I would like to thank my academic supervisor, Dr Paul Morris for his advice and feedback throughout this project. I would also like to thank Dr Ethel Quayle for her thoughtful input. Thank you to Rowena Stewart, Liaison Librarian at the University of Edinburgh for her advice regarding electronic database searches.

An enormous thank you goes to Dr Melanie Platten, who has continuously provided me with encouragement, ideas and advice. Thank you for the huge investment you made in this project, your input has been invaluable. Thank you for your constant calming presence. I would also like to thank, Dr John Higgon for his advice and for listening to a subset of the IPT sessions.

Special thanks go to my Mum and Dad, without your unconditional love and support none of this would have been possible. To my family, thank you for keeping my feet on the ground and reminding me what is important. Thank you to all of my understanding friends who have been there to keep me positive.

To Matthew, my biggest thanks go to you for being patient and understanding. You always believed in me and without your support and encouragement I could not have done this!

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Word count for full thesis (including tables and figures): 21,493

Full Thesis Abstract

Post-stroke depression (PSD) is highly prevalent and has a significant impact on stroke patients' recovery.

The systematic review aimed to build on previous review evidence to investigate the effectiveness of psychosocial interventions on reducing depression levels post-stroke. Multiple electronic databases were searched using a combination of keywords related to depression, stroke and psychosocial interventions. Randomised controlled trials investigating the effect of psychosocial interventions on depression levels for adult stroke patients were included. Methodological quality of included studies was assessed using criteria developed by the authors. Sixteen studies were included, four of which found a significant benefit of psychosocial interventions over control conditions on mood. While the results suggest some psychosocial interventions may be effective in reducing depression post-stroke; confidence in these findings is limited due to methodological limitations within studies. The review identified a number of methodological limitations across all included studies which may explain why previous research has not found any benefit of psychosocial interventions for PSD. Therefore, the evidence base is currently insufficient and further research which utilises a robust methodology is needed before any reliable conclusions can be drawn regarding the effectiveness of psychosocial interventions for PSD.

The empirical study aimed to explore participants' experiences of an Interpersonal Psychotherapy (IPT) assessment and formulation post-stroke to investigate the acceptability of using this model with patients experiencing PSD and indicate if more detailed quantitative research is justified. Ten participants with post-stroke

depression (PSD) received two assessment appointments with a Clinical Psychologist, generating an IPT formulation of their difficulties. Participants subsequently took part in a semi-structured interview about their experience of this process. The results of these interviews were transcribed and analysed using Framework Analysis. Participants were seen to link their difficulties post-stroke to three of the four IPT interpersonal focus areas; interpersonal disputes, role transitions and grief loss. Overall, participants found an IPT assessment and formulation to be acceptable and identified benefits of the sessions including: altering their viewpoint, increasing acceptance of impaired functioning, reducing frustration, increasing positive feelings and leading to improvements in their social support. IPT may therefore be a suitable intervention for PSD and further robust, quantitative research is justifiable. Results suggest acceptance and an altered viewpoint are common following an IPT assessment and formulation; therefore future IPT research should measure changes in these variables alongside mood and behaviour.

1. The clinical effectiveness of psychosocial interventions for reducing depression scores post-stroke: a systematic review

Journal Format: Clinical Rehabilitation

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Word count: 5,757

1.1 Abstract:

Objectives: Post-stroke depression (PSD) is highly prevalent and has a significant impact on patients' recovery; however the evidence for the effectiveness of psychosocial interventions for PSD is inconclusive. This systematic review aimed to build on previous review evidence by including updated research and broadening the inclusion criteria to investigate the effectiveness of psychosocial interventions in reducing depression levels post-stroke.

Data sources: Electronic databases (*PsychoINFO, Medline, CINAHL & EMBASE*) were searched using a combination of keywords related to depression, stroke and psychosocial interventions. Key journals and the reference lists of included studies and other review articles were hand searched. First authors of included studies were contacted to include unpublished research.

Review methods: Randomised controlled trials investigating the effect of psychosocial interventions on depression levels for adult stroke patients were included. Methodological quality of included studies was assessed using criteria developed by the authors.

Results: Sixteen studies met the review's inclusion criteria, four of which found a significant benefit of psychosocial intervention over control conditions on mood. However, methodological limitations lead to difficulties generalising these findings. The review identified a number of methodological limitations across all included studies which may explain why previous research has not found any benefit of psychosocial interventions for PSD.

Conclusions: The evidence base for the effectiveness of psychosocial interventions in reducing PSD is currently insufficient and further research which utilises a robust methodology is needed before any reliable conclusions can be drawn regarding the effectiveness of psychosocial interventions for PSD.

Key words: Stroke, depression, psychosocial interventions, systematic review

1.2 Introduction

In the UK, approximately 130,000 people are affected by Stroke per year.¹ Stroke is the 'leading cause of adult disability'^{2(p6)} and 'one of the top three causes of death'^{2(p6)} in the UK. Approximately one third of all stroke patients go on to experience depression which significantly impacts on their ability to recover after a stroke.^{3,4} Correlates of post-stroke depression (PSD) include: reduced quality of life, increased cognitive impairment, delayed functional recovery, increased health care usage, increased social isolation, increased suicidality and increased risk of mortality.^{1,4,5}

1.2.1 Treatments for PSD

Research into treatments for PSD has generally focussed on pharmaceutical interventions.⁶ Antidepressant medication has been found to be an effective treatment for PSD, counteracting the negative consequences of PSD and leading to decreased mortality and enhanced physical and cognitive recovery.⁷ A recent Cochrane meta-analysis⁸ into interventions for PSD including pharmaceutical interventions, electroconvulsive treatment and psychological interventions found that antidepressant medication did have some benefits in treating PSD, yet the effect size was generally small. They also identified that antidepressant medication should be used with caution due to the associated side effects.⁸ The use of antidepressant medication in clinical practice is surrounded with many issues around optimal dosage, risk of relapse, length of treatment and choice of medication.⁹ Antidepressant medication has also been found to be associated with a 48% increased risk of experiencing a stroke.¹⁰ It has therefore been suggested that antidepressant

medication should be used with caution and reserved for stroke patients with severe and persistent depressive disorder.^{8,11}

Although psychological interventions have been found to be effective treatments for depression in non-stroke populations such as working-aged adults, older adults, general medical disordered patients, chronic depressed patients and patients with sub-threshold depression; psychological interventions for PSD have received little investigation.^{6,12} The previous Cochrane meta-analysis⁸ evaluated four randomised control trials (RCTs) investigating psychotherapy interventions for PSD and found no evidence for the effectiveness of psychotherapy for PSD. A lack of consistency among psychotherapy research in terms of therapist training and adherence to the therapeutic model may have impacted on their findings.⁸ However, despite these findings ‘The Matrix: A guide to delivering evidence-based psychological therapies in Scotland’¹³ ‘recommends’ the use of CBT for PSD. While, the Scottish Intercollegiate Guidelines Network⁹ acknowledged that there was insufficient evidence for the benefit of psychological interventions for PSD, they have included talking-based therapies in their clinical practice recommendations for treating PSD based on the clinical experiences of the guideline development group. These recommendations imply that there is an evidence base for some psychosocial interventions for PSD despite the lack of robust evidence.

1.2.2 Need for the current review

PSD continues to be highly prevalent and has a significant impact on stroke patients’ recovery, yet the evidence for the effectiveness of psychotherapy for PSD is still inconclusive.^{5,6} The overall prevalence of stroke is rising, mainly due to the general

shift towards an ageing demographic.¹⁴ It is therefore important to identify effective treatments for PSD and improve outcomes for patients post-stroke.

The current review focuses solely on psychosocial interventions for PSD as a similar review does not appear to have been conducted. A number of reviews have examined ‘therapeutic’ interventions for PSD but have included a mixture of interventions such as music therapy, exercise programmes, social support interventions and rehabilitation therapy.^{4,15,16,17} Kneebone and Dunmore¹⁸ conducted a review of psychological interventions for PSD, but did not use a systematic methodology and did not focus solely on RCTs.

The recent Cochrane meta-analysis,⁸ looking at different interventions for PSD, included a stroke population that had depression (diagnosed by clinician, psychiatric interview or mood scale) and excluded studies which included stroke patients who were not clinically depressed. A further Cochrane review¹⁹ looked at interventions for preventing PSD but excluded studies which included depressed patients. Therefore, there appears to be a gap in the review literature for a review which investigates the effectiveness of an intervention on depression levels regardless of depression diagnosis. A large number of intervention studies have included both depressed and non-depressed stroke patients in their sample. Therefore broadening the review population will include a wider number of studies. The authors of the Cochrane review⁸ noted that a broader group of stroke patients should be included in future research to make the findings more generalisable. Psychotherapy has been found to be an effective treatment for depression in non-stroke populations including patients with sub-threshold depression¹²; therefore broadening the review population

may be useful. A number of relevant RCTs have also been carried out since the Cochrane meta-analysis⁸ was published.

A recent unpublished systematic review¹⁷ examined methodological issues within existing research into non-pharmacological interventions for PSD. Picton¹⁷ included a stroke population that had depression and did not restrict their search to RCTs or psychosocial interventions. The current review primarily aimed to investigate the effectiveness of psychosocial interventions in reducing depression levels post-stroke although the methodological quality of included studies was also considered.

1.3 Objective

To examine RCT interventions to determine whether psychosocial interventions for patients post-stroke lead to a reduction in depressive symptoms when compared to controls.

1.4 Method

To confirm that a similar systematic review had not recently been completed or was planned, the Cochrane Library was searched with the terms; ‘Stroke AND depression’ and ‘stroke AND mood’. This search revealed six review articles which were loosely related to the current review including the two Cochrane reviews^{8,19} and the reviews by Graven et al¹⁵ and Salter et al⁴ described above. The search identified a review by Cole et al²⁰ which investigated the effectiveness of antidepressant treatments for PSD; no psychosocial intervention studies were evaluated and the search was not restricted to RCTs. The final identified review by Yu et al²¹ was unavailable in English.

The guidelines produced by Centre for Reviews and Dissemination²², Scottish Intercollegiate Guidelines Network²³ (SIGN 50) and The PRISMA Group²⁴ were consulted when conducting the current systematic review.

1.4.1 Inclusion and exclusion criteria

1.4.1.1 Study design

The review was restricted to RCTs investigating psychosocial interventions for stroke patients. RCTs limit the risk of bias and are considered as the most appropriate design to evaluate the effects of an intervention.²²

The current review did not restrict studies based on length of follow-up, size of sample or publication status. RCTs that did not report baseline depression levels for each intervention group were excluded.

1.4.1.2 Population

Studies were restricted to adult participants (aged 18 or over) that had experienced a stroke. No specific restrictions were placed on type of stroke although RCTs were excluded if a large proportion (>10%) of participants had experienced a subarachnoid haemorrhage (SAH) as this subtype of stroke often has a different presentation and management.⁸ Studies which included both stroke and non-stroke patients were only included if separate results were available for stroke patients. No restrictions were placed in terms of length of time that had passed since stroke or where the participants were currently living.

RCTs were not restricted to studies which required participants to have a diagnosis of depression for inclusion into the study. Studies were excluded from the review if they excluded participants with depression as it was agreed that these studies were not interested in treating depression.

1.4.1.3 Interventions

For the purpose of this review the definition of a psychosocial intervention used in the recent Cochrane meta-analysis^{8(p4)} was chosen: ‘interventions had to have a psychological component - talking, listening, support, advice; be based on a theory of talking therapy; be structured and timetabled as a talking therapy’. The content of the interventions varied ‘from counselling to specific psychotherapy’.^{8(p4)} Studies were excluded if the sole purpose of the intervention was to provide information/education, occupational therapy or rehabilitation services ‘unless there was a clearly defined psychological component’.^{8(p4)}

Psychosocial interventions which were not actively targeting depression but which measured the effectiveness of the intervention on depression levels were also included. Interventions which were solely aimed at caregivers were excluded although interventions where caregivers joined stroke patients to receive the intervention were included if there was separate data available for stroke patients. Unstructured interventions were excluded if it was unclear if all participants in the intervention group received the psychosocial aspect of the treatment.

Open discussions between contributing clinicians were carried out to reduce the subjective bias in identifying papers which met the criteria for a psychosocial intervention.

1.4.1.4 Comparators

No restrictions were placed in terms of the control groups used by studies. We did not exclude studies which compared more than one active intervention to each other.

1.4.1.5 Outcome measures

Studies which assessed the clinical effectiveness of interventions using self-report/observer validated measures of depression were eligible for inclusion.

1.4.2 Literature Search Strategies

The literature search was initially conducted in August 2013. The following electronic databases were searched: PsychoINFO (1987-2013); CINHAL (1937-2013); EMBASE (1980-2013); Medline (1966-2013). While the exact terms used varied due to differences in index terms across databases, the search strategy remained the same. Each of the databases were searched for all the different terms for “stroke” which were combined with OR commands, all the different terms for “depression” (combined using OR), and all the different terms to encapsulate “psychosocial interventions” (combined using OR). These three search areas were then combined using AND commands to make sure the final search included all the terms for depression AND all the terms for stroke AND all the terms for psychosocial intervention. On EMBASE, Medline, CINHAL the search was limited to RCTs only. This limiter was unavailable on PsychoINFO. A copy of the full search criteria used in one of the electronic databases is detailed in the Appendix A. The full search criteria used in each of the four databases is available on request from the author. The literature searches were conducted again in February 2014 using the

same search strategy to identify any articles published since August 2013. Only studies published in English were included.

Reference lists of the articles included in the current review and relevant existing review articles were scanned. This identified one eligible published study which was not detected by the database search as it did not include a term for depression as a keyword or within the title or abstract. The lead authors of the included studies were contacted to request any unpublished studies to reduce publication bias. Contact details for lead authors were unavailable for two of the included studies; therefore on these occasions the second author was contacted. Lead authors of published RCT protocols which appeared appropriate for inclusion within the current review were also contacted. Of the eighteen authors that were approached, fifteen responded and suggested 25 articles (published and unpublished), however no additional studies were identified that met the inclusion criteria and currently had data available. Relevant journals; *Stroke*, *Clinical Rehabilitation*, *Journal of Stroke and Cerebrovascular Disease*, *International Journal of Stroke* and *Topics in Stroke Rehabilitation*, within the years (2009-Feb 2014), were hand searched. This identified six studies which met criteria for inclusion, though each of these had already been identified from the electronic database search.

1.4.3 Data extraction

Guidance from Schulz, Altman and Moher,²⁵ the Centre for Reviews and Dissemination²² and Scottish Intercollegiate Guidelines Network²³ were used to design an extraction form to examine key study characteristics. First authors were contacted if information was unavailable from the published material.

If effect sizes for the depression outcome measures, comparing pre- and post-intervention and follow-up for the intervention group were not reported, they were calculated using the Cohen's d formula: $[(\text{pre-intervention mean} - \text{post-intervention (or follow-up) mean}) / \text{pooled standard deviation (SD)}]$. If the mean and SD were not documented in the published articles, first authors were contacted to provide this information and on occasions where the median and interquartile ranges for depression outcomes were reported, the mean and SD were estimated using a method suggested by Huzo et al²⁶

1.4.4 Assessment of quality of reviewed studies

There is no single approach for addressing methodological quality in systematic reviews, it is therefore important to review possible criteria and guidance in the area and tailor the criteria to the review question.²² The quality criteria used in the current review were developed by the contributing clinicians in collaboration and were based on existing guidance.^{22,23,25} For each of the 12 criterion the studies were classified as one of six outcome ratings used by Scottish Intercollegiate Guidelines Network;^{23(p64)} 'well covered' (2 points), 'adequately addressed' (1 point), 'poorly addressed', 'not addressed', 'not reported' or 'not applicable' (all 0 points) (definitions of each of the six classifications for each criterion is available from the author). RC rated the methodological quality of all 16 studies and PGM independently rated a random selection of four of the studies. The ratings led to an exact agreement on 87.5% of the methodological items rated (42/48), with a difference of one point (e.g. adequately addressed versus poorly addressed) on 12.5% (6/48) of items rated.

Where there were discrepancies between raters, the criteria was reviewed and amended where appropriate.

1.5 Results

The search process identified 2,379 potential studies. Titles and abstracts were screened for their eligibility based on the inclusion and exclusion criteria and duplicates were removed. This resulted in 141 studies which were further reviewed for inclusion by reading the full article; following this 125 studies were excluded. The final review included 16 studies. See Figure 1 and Table 1 for more details of the search flow.

Table 1: Source of included studies

Sources of Studies	Number of articles initially screened for inclusion	Number of studies included in this review	Review study number
PsychoINFO	488	8	1, 3, 4, 5, 16, 11, 12, 13
EMBASE	278	9	2, 3, 4, 5, 7, 9, 14, 15, 16
Medline	186	8	1, 2, 3, 4, 5, 6, 7, 14
CINHAIL	40	8	1, 2, 3, 4, 5, 7, 8, 16
Papers suggested after contacting first authors of relevant articles	25	4	3, 4, 14, 15
Journals hand-searched (2009-Feb 2014)			
<i>Stroke</i>	7	3	2, 4, 15
<i>Journal of Stroke and Cerebrovascular Diseases</i>	1	0	
<i>Clinical Rehabilitation</i>	4	2	4, 16
<i>Topics in Stroke Rehabilitation</i>	4	1	3
<i>International Journal of Stroke</i>	8	3	4, 9, 16
Search of reference lists from included articles	760	7	2, 4, 5, 7, 10, 11, 12
Search of reference lists from relevant reviews	578	9	2, 5, 6, 7, 8, 11, 12, 13, 10
All sources	2,379	16	

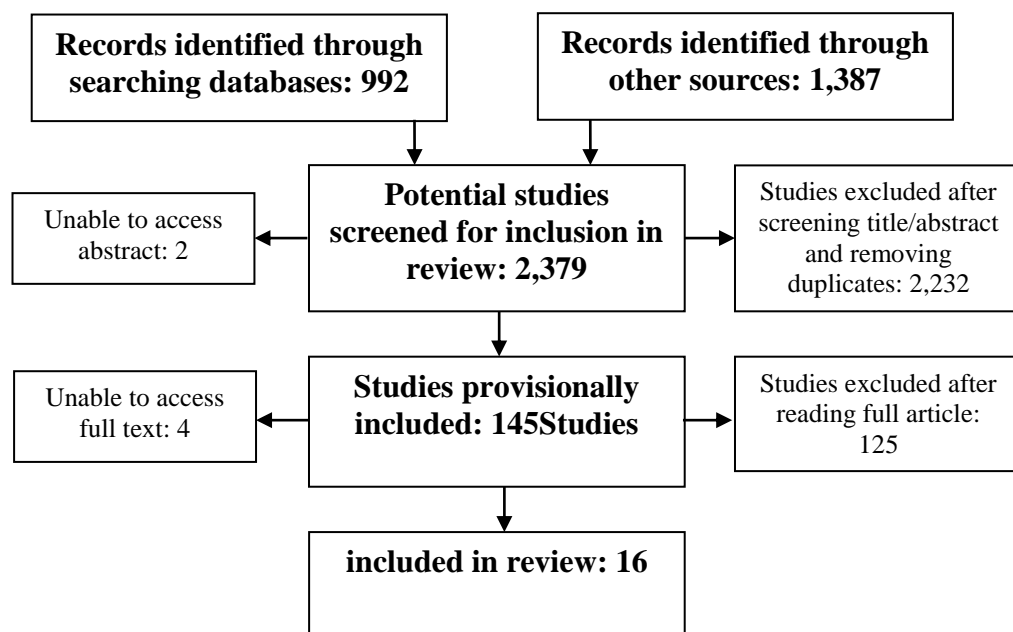


Figure 1: Literature search process flow chart

Table 2: Summary of the key findings of included studies

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
<i>Studies which only included participants with a diagnosis of depression:</i>										
1. Alexopoulos et al. ²⁷ America	Rehabilitation hospital	Ecosystem Focused Therapy (EFT): education and direct suggestions for developing an adherence enhancement structure. Problem solving training.	12 weekly 45 minute session.	Education on Stroke Depression (ESD)	EFT (9) ESD (11)	Hamilton Depression Rating Scale (HDRS)	0	1.52	n/a	Greater decline in depressive symptoms over time for EFT over ESD, although not significant.
2. Lincoln & Flannaghan ²⁸ United Kingdom	Acute hospital	Cognitive Behavioural Therapy (CBT)	10 one hour sessions over 3 months	Control (C) + Attention Placebo (AP): 10 sessions over 3 months with no therapeutic content	CBT (34) C (36) AP (41)	Beck Depression Inventory (BDI)	3	2.10*	1.69*	No Significant difference between the groups in mood post-treatment and at 3-month follow-up.
3. Mitchell et al. ²⁹ America	Acute hospital	Psychosocial Intervention (PI) - provided with written materials based on Social Learning and Gerontologic Theory. Aimed to increase pleasant and social activity. Included problem-solving skills.	9 sessions over 8 weeks	Usual Care (UC)	10months PI (44) UC (48) 22months PI (34) UC (33)	Hamilton Depression Rating Scale (HDRS)	3, 10 (primary end point) & 22 (small n)	1.98	10months: 1.72 22months: 2.18	Remission rates (HDRS<10) were significantly greater for PI compared with UC at post-treatment and 10 month follow-up. The decrease in HDRS at 10 months was significant for PI compared to UC.

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

•Unable to calculate from information provided in published material and no response from first author.

Table 2. (continued) (Studies which only included participants with a diagnosis of depression)

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
4. Thomas et al ³⁰ United Kingdom	Acute hospital, community stroke rehabilitation services, Speech and Language Therapy, stroke & communication groups in the community	Behavioural Therapy (BT): education, activity monitoring, activity scheduling, and graded task assignments.	Up to 20 sessions over three months with each session lasting an hour	Usual Care (UC)	BT (43) UC (46)	Stroke Aphasic Depression Questionn- aire-21 Hospital Version (SADQH- 21)	3	0.57	0.53	When baseline values were controlled, allocation to BT compared with UC significantly predicted better SADQH-21 post- treatment & at 3- month follow-up.
5. Towle et al ³¹ United Kingdom	Acute Hospital	Psychosocial Intervention (PI): Information booklet looking at housing, financial benefits, self- help groups, aids for daily living plus counselling from a social worker where participants reflected on their situation.	Up to twice a week for 16 weeks.	Information booklet plus one visit from social worker to give them the workbook	PI (16) Control (18)	General Health Questionn- aire (GHQ- 28)	0	0.79*	n/a	No significant difference between the intervention groups on Wakefield Self- Assessment of Depression Inventory (WDI) or GHQ-28 post- treatment.

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

♦Unable to calculate from information provided in published material and no response from first author.

Table 2. (continued)

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
<i>Studies with mixed samples of both depressed and non-depressed stroke patients:</i>										
6. Aben et al ³² Netherlands	Rehabilitation Centres	Memory Self Efficacy Training (MSET): group intervention, taught to use memory strategies and are educated on the influence of negative perceptual bias in memory demanding situation. Used CBT aspects. Participants received booklet with information about the group sessions. Also given half an hour homework assignments	Nine groups were held, twice weekly, lasting 1 hour.	Peer Support (PS): general education on causes and consequence of stroke. No active therapeutic interventions.	MSET (77) PS (76)	Centre for Epidemiologic Studies Depression Scale (CES-D)	10 days after the intervention	♦	n/a	No significant effect between intervention group and time on depression score
7. Chang et al ³³ China	Rehabilitation Centre	Psychosocial Intervention (PI): usual care + counselling. Included: education, a behavioural training component using rational emotive behaviour therapy, belief changes and anger management.	4 weekly sessions lasting 1-2 hours	Usual Care (UC)	PI (34) UC (32)	Chinese Version of the Hamilton Depression Scale (HDRS)	0	0.68	n/a	PI showed significantly greater improvement in depression scores than UC post-treatment.
8. Clark et al ³⁴ Australia	Inpatient rehabilitation hospital	Psychosocial Intervention (PI): Information package plus three visits from a social worker who was trained in family counselling techniques.	Three one hour sessions. First occurred three weeks after discharge, second at two months and third at five months post- discharge.	Usual Care (UC)	PI (32) UC (30)	Geriatric Depression Scale Short Form (GDI-15)	1	n/a	-0.44	No significant effect of intervention group on depression scores at follow-up.

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

♦Unable to calculate from information provided in published material and no response from first author.

Table 2. (continued) *(Studies with mixed samples of both depressed and non-depressed stroke patients)*

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
9. Eames et al ³⁵ <i>Australia</i>	Stroke unit.	Psychosocial Intervention (PI): Education and support package; tailored education booklet given during a face-to face contact. Participants also received up to 3 telephone contacts to verbally reinforce the information. Informed by health beliefs model and adult learning principles to explore and overcome barriers, providing reassurance and encouragement, stress management strategies.	Three Telephone calls at one month intervals over 3 months	Usual Care (UC)	PI (35) UC (31)	Hospital Anxiety and Depression Scale – Depression Subscale (HADS)	0	-0.24	n/a	There was no significant difference between conditions post- treatment on HADS-D.
10. Forster & Young ³⁶ <i>United kingdom</i>	Acute hospital, Speech therapy register, liaison with community physiotherapists, district nurses	Psychosocial Intervention (PI): Visits from a specialist outreach nurse providing support and information. Reviewing problems, goal setting, maximising social activities and advice on benefits and driving.	Visits over a 12 month period. Visit 1: within one week of recruitment. Visit 2: one week later. Visit 3- one month later. Visit 4- two months later. Visit 5- three months later. Visit 6 –six months later. Visit 7- 12 months	Usual Care (UC)	PI (88) UC (89)	Nottingham Health Profile	0	-0.17*	n/a	There were no significant differences within or between the groups found on the depression outcome measure. The number of patients in both groups who scored over 30 (indicating depressed mood) remained similar

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

•Unable to calculate from information provided in published material and no response from first author.

Table 2. (continued) (*Studies with mixed samples of both depressed and non-depressed stroke patients*)

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
11. Frank et al ³⁷ <i>United Kingdom</i>	General Practitioners, consultants in stroke and physical disability, Occupational Therapists and a local stroke club	Psychosocial Intervention (PI): Workbook intervention plus facilitator sessions to: provide information, enhance coping, planning and problem-solving skills. Relaxation tape	5 weekly contacts with facilitators. First two session were face-to-face, the last three contacts were telephone contacts	Waiting List Controls (WLC) who received the workbook after the trial	WLC (20) PI (19)	Hospital Anxiety and Depression Scale – Depression Subscale (HADS)	0	0.14	n/a	There was no significant effect of intervention group by time on the HADS-D scores.
12. Johnston et al ³⁸ <i>United Kingdom</i>	Acute hospital	Psychosocial Intervention (PI): Workbook plus five sessions to monitor goals and achievements and provided encouragement. The CBT workbook provided information about stroke and guidance on coping skills. Diary sheets and relaxation tape used.	5 weekly sessions	Usual Care (UC)	PI (74) UC (84)	Hospital Anxiety and Depression Scale (HADS)	4	0.10	0.27	No significant effect was found of intervention group by time on the total HADS or the HAD-D separately.
13. Kendall et al ³⁹ <i>Australia</i>	Acute hospital	Chronic Disease Self- Management (CDSM): healthy eating, exercise, relaxation, reinforcing solution focused behaviours (problem-solving, goal setting, communication with health care team and family)	Groups were held weekly for 6 weeks for 2 hours each. 10-15 participants per group	Usual Care (UC)	*n at baseline CDSM (58) UC (42)	Stroke Specific Quality of life Scale (SSQOL) mood subscale	9	-0.12	-0.21	No significant effect of intervention group by time on patient's mood.

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

♦Unable to calculate from information provided in published material and no response from first author.

Table 2. (continued) (*Studies with mixed samples of both depressed and non-depressed stroke patients*)

Study Country	Sample recruited from	Details of intervention	Structure of intervention	Details of control/ usual care arm	(n) at follow- up	Primary depression outcome measure	Follow- up time period (months)	Pre- Post- treatment Effect Size (d) for intervention group	Pre- Follow-up Effect size (d) for intervention group	Key Finding
14. Ostwald et al ⁴⁰ <i>America</i>	Health care systems.	Home-Based (HB): stroke survivors and carer dyads received personalised mailed information plus home visits using 39 pre-determined protocols providing education, support, counselling, skills training and also signposting to local resources.	Over 6 months each dyad received approximately 16 visits of 70 minutes each.	Mailed (M): information on signs and symptoms of stroke, stroke prevention, stress reduction strategies and tips for leisure activity adaptations.	HB (69) M (65)	Geriatric Depression Scale (GDS)	6	0.16	0.21	No significant difference between intervention groups on GDS post-treatment or at 6-m follow-up. Both intervention groups showed a reduction in GDS scores over time.
15. Rochette et al ⁴¹ <i>Canada</i>	Acute Hospitals	WE CALL: multimodal support intervention (telephone, internet, paper). Based on Family Intervention Telephone Tracking Model. Reinforcing problem solving skills and using counselling skills. Looking at family functioning, depression, physical health, neurocognitive functioning, independence and risk factors	Telephone calls weekly for first two months, fortnightly during third month and monthly for final three months. Telephone contacts lasted 15-20 minutes	YOU CALL: participants given contact details for a trained health care professional they could contact to discuss topics of their choice	We call (69) You call (70)	Beck Depression Inventory (BDI-II)	6	♦	♦	No significant difference between treatment groups in terms of mood post-intervention or at six-month follow up. Although both groups' mood improved from baseline.
16. Watkins et al ⁵ <i>United Kingdom</i>	Acute hospital	Motivational Interviewing (MI)	Up to 4 weekly 30-60 minute sessions	Usual Care (UC)	MI (164) UC (156)	General Health Questionnaire (GHQ-28)	11	♦	♦	MI had a significant benefit over UC in improving mood at 2- and 11-month follow-up.

* To calculate effect size, mean and SD were calculated from median and interquartile range using Hozo *et al.* (2005)²⁶

♦Unable to calculate from information provided in published material and no response from first author.

Table 3: Quality ratings for included studies

Study	Quality Criteria												Quality 'Score' (/24)
	1. Repres- entative Sample	2. Baseline Assessed	3. Attrition	4. Randomi- sation	5. Sample Size	6. Follow- up	7. Outcome Measure	8. Intervent- ion Defined	9. Fidelity	10. Therapist Training	11. Control group	12. Statistical Analysis	
Studies which only included participants with a diagnosis of depression:													
Alexopoulos et al ²⁷	Adequately addressed	Well covered	Adequately addressed	Adequately addressed	Poorly addressed	Not addressed	¹ Well covered	Adequately addressed	Adequately addressed	Adequately addressed	Adequately addressed	Adequately addressed	11
Lincoln & Flannaghan ²⁸	Well covered	Well covered	Well covered	Well covered	Poorly addressed	Poorly addressed	Well covered	Adequately addressed	Not reported	Not reported	Well covered	Adequately addressed	14
Mitchell et al ²⁹	Adequately addressed	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Well covered	Adequately addressed	Not reported	Not reported	Well covered	Adequately addressed	16
Thomas et al ³⁰	Adequately addressed	Well covered	Well covered	Well covered	Adequately addressed	Poorly addressed	¹ Well covered	Adequately addressed	Well covered	Adequately addressed	Well covered	Adequately addressed	16
Towle et al ³¹	Adequately addressed	Well covered	Adequately addressed	Well covered	Poorly addressed	Not addressed	Adequately addressed	Poorly addressed	Not reported	Not reported	Adequately addressed	Poorly addressed	8
Studies with mixed samples of both depressed and non-depressed stroke patients:													
Aben et al ³²	Adequately addressed	Well covered	Well covered	Adequately addressed	Well covered	Not addressed	Well covered	Adequately addressed	Not Reported	Not reported	Adequately addressed	Well covered	14
Chang et al ³³	Adequately addressed	Well covered	Well covered	Adequately addressed	Poorly addressed	Not addressed	¹ Well covered	Adequately addressed	Not reported	Not reported	Well covered	Adequately addressed	11
Clark et al ³⁴	Poorly addressed	Adequately addressed	Well covered	Well covered	Poorly addressed	Poorly addressed	Well covered	Adequately addressed	Not reported	Adequately addressed	Well covered	Adequately addressed	12
Eames et al ³⁵	Adequately addressed	Not addressed	Well covered	Well covered	Poorly addressed	Not addressed	Well covered	Adequately addressed	Not reported	Adequately addressed	Well covered	Adequately addressed	12
Forster & Young ³⁶	Adequately addressed	Poorly addressed	Well covered	Well covered	Well covered	Not addressed	Adequately addressed	Adequately addressed	Not reported	Adequately addressed	Well covered	Adequately addressed	13
Frank et al ³⁷	Adequately addressed	Adequately addressed	Well covered	Adequately addressed	Poorly addressed	Not addressed	Well covered	Poorly addressed	Not reported	Not reported	Well covered	Adequately addressed	10

Table 3. (continued)

Study	Quality Criteria												Quality 'Score' (/24)
	1. Representative Sample	2. Baseline Assessed	3. Attrition	4. Randomisation	5. Sample Size	6. Follow-up	7. Outcome Measure	8. Intervention Defined	9. Fidelity	10. Therapist Training	11. Control group	12. Statistical Analysis	
Johnston et al ³⁸	Well covered	Well covered	Adequately addressed	Adequately addressed	Well covered	Poorly addressed	Well covered	Poorly addressed	Not reported	Not reported	Well covered	Adequately addressed	13
Kendall et al ³⁹	Adequately addressed	Adequately addressed	Not reported	Adequately addressed	Not reported	Adequately addressed	Adequately addressed	Adequately addressed	Not reported	Adequately addressed	Well covered	Well covered	11
Ostwald et al ⁴⁰	Poorly addressed	Well covered	Well covered	Adequately addressed	Well covered	Adequately addressed	Well covered	Poorly addressed	Not Reported	Not reported	Adequately addressed	Adequately addressed	12
Rochette et al ⁴¹	Poorly addressed	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Adequately addressed	Not reported	Not reported	Adequately addressed	Well covered	15
Watkins et al ⁵	Well covered	Adequately addressed	Well covered	Well covered	Well covered	Adequately addressed	Adequately addressed	Poorly addressed	Well covered	Adequately addressed	Well covered	Adequately addressed	17

- 1 The sample selected were representative of wider clinical population
- 2 Participants in each condition are similar at baseline in terms of depression levels or differences were controlled for in analyses
- 3 Levels of attrition were reported and equivalent for each condition
- 4 Randomised assignment to treatment groups
- 5 Sample size was sufficient for analyses relating to depression outcomes
- 6 Follow-up assessment was for a suitable time period after intervention
- 7 A suitably robust measure of depression was used (¹one point deduction if the depression outcome measure used was not self-report and was rated by a researcher or carer who was not blinded to the participants group allocation or where blinding was not reported for studies with observer rated measures of depression).
- 8 Intervention sufficiently defined
- 9 Intervention delivered as planned/ compliance checked
- 10 The therapist delivering the intervention had adequate training/ competence
- 11 A control group was used
- 12 The analysis method used was appropriate to the design used and depression outcome measure

1.5.1 Quality of included studies

The quality ratings for each of the 16 included studies are provided in Table 3.

1.5.1.1 Population

The mean age of participants across included studies ranged from 51.2 years to 68.2 years. Five of the included studies included depression as an inclusion criterion.²⁷⁻³¹

The results of these five studies are presented at the top of both Table 2 and Table 3 to aid comparison across studies. The remaining eleven studies included a mixture of both depressed and non-depressed stroke patients in their samples.

Thirteen of the included studies applied inclusion/exclusion criteria which limited the generalisability of their findings. Common criteria used included excluding participants who lived in residential care.^{27,31,32,34,35,39} Eames et al³⁵ and Ostwald et al⁴⁰ only included participants who were discharged home to a spouse while Kendall et al³⁹ only included participants who had a friend willing to participate. Further inclusion/ exclusion criteria involved only including post-stroke patients with aphasia,³⁰ mild stroke,⁴¹ first stroke episode,^{39,41} experiencing a stroke related disability³⁶ or needing help with daily living.⁴⁰ Aben et al³² only included post-stroke patients with a memory complaint while nine studies excluded participants with communication or cognitive problems.^{5,27,29,31,33,34,37,40,41}

1.5.1.2 Study Design

The included studies reported relatively short follow-up periods, with 10 of the studies having a follow-up period of three months or less. While some studies indicated longer follow-up periods, these time periods included the intervention too.

Only three studies were rated as “well covered” for their statistical analysis and management of missing data.^{32,39,41} Five studies did not record using any statistical methods to appropriately manage missing data. For four of these studies the attrition rates were relatively small (less than 20% of the total participants),^{28,33,34,37} while the attrition rates for Towle et al³¹ exceeded 20% of the total participants. The remaining eight studies^{5,27,29,30,35,36,38,40} described using intention-to-treat (ITT) analysis; however it was unclear in the published material which data they had used to replace missing data. Using an inappropriate method to replace missing data can bias results e.g. carrying the “last score carried forward” may bias results if studies carry participants’ scores forward from post-intervention to follow-up. Studies were rated as ‘adequately addressed’ if they described using ITT analysis but did not specify the method used.

1.5.1.3 Outcome Measures

The authors examined the psychometric properties of the depression outcome measures used by all included studies. Overall, the measures of depression had acceptable validity and reliability although four of the studies may not have used the most valid measures of depression for a stroke population.^{5,31,36,39} The majority of the studies used self-report measures of depression and this reduces the need for those administering the measures to be blind to the treatment condition. However, four of the included studies used outcome measures for depression that were rated by an observer and only one of these studies²⁹ made reference to appropriate concealment to allocation. One point was therefore deducted from three studies on quality criteria seven.^{27,30,33}

1.5.1.4 Interventions

While some of the studies included similar psychosocial components in their interventions, no two studies evaluated identical interventions. Two of the included studies were group interventions.^{32,39} Ten of the studies included stroke patients and carers/spouses in their interventions.^{27,29,31,34-40}

The majority of the contacts with the therapists in the intervention groups were face-to-face, although the Eames et al³⁵ and Frank et al³⁷ included telephone contacts. Rochette et al⁴¹ solely included telephone contacts. Duration of the intervention ranged from one to 12 months, with the number of sessions per intervention ranging from three to 32 sessions. The majority of interventions included weekly sessions which lasted approximately one hour, although the length of each session ranged from 15 to 120 minutes. The frequencies of the interventions were often tailored to fit the needs of the individuals. Six studies did not specify the length of each session.^{29,31,35-38}

Seven of the included studies mentioned the use of antidepressant medication alongside the psychosocial intervention;^{27-30,33,35,36} the remaining nine studies did not comment on the use of antidepressant medication.

It seems likely that the included studies could not be replicated in all important aspects based on the information provided in the published materials. Only three studies reported measures of treatment fidelity, with Alexopoulos et al²⁷ including one measure of treatment fidelity whilst Thomas et al³⁰ and Watkins et al⁵ both reported carrying out two or more measures of treatment fidelity. Only seven

studies^{5,27,30,34-36,39} provided any details regarding the training therapist received in relation to the intervention; the training therapists received tended to be very brief.

1.5.2 Effectiveness of psychosocial interventions for patients post-stroke within the context of methodological quality

It was not possible to compare the different effect sizes reported by included studies: therefore, effect sizes at pre- and post-intervention and follow-up for the intervention group only were calculated to allow comparison across studies. Effect sizes could not be calculated for Aben et al,³² Rochette et al⁴¹ and Watkins et al⁵ due to insufficient details despite efforts to contact the authors of these studies for further information.

As studies which included only depressed participants would have more scope to demonstrate change in depression than those which included non-depressed participants, we have presented the findings of these two groups separately.

1.5.2.1 Samples containing only depressed participants:

Five of the studies included only participants with depression, all of which were calculated to have high^{27-29,31} to medium³⁰ effect sizes for the improvement in depression scores pre- and post-intervention for the intervention group. Large to medium effect sizes for the improvement in depression scores pre-intervention versus follow-up for the intervention group were also calculated for: Lincoln and Flannaghan²⁸ (3-month follow-up), Mitchell et al²⁹ (10- and 22-month follow-up) and Thomas et al³⁰ (3-month follow-up).

However, when comparing the change in depression scores over time for the intervention and control groups; only Mitchell et al²⁹ and Thomas et al³⁰ found a

statistically significant improvement in the intervention group when compared to the control group. For Thomas et al³⁰ the improvement in depression scores between groups from pre-intervention was statistically significant post-intervention and at three-month follow-up. For Mitchell et al²⁹ this improvement in depression scores was found to be statistically significant between groups from pre-intervention to post-intervention and 10-month follow-up. For Mitchell et al²⁹ the difference between groups in terms of improvement in depression scores was not statistically significant at 22-month follow-up; possibly due to high attrition rates. Both Mitchell et al²⁹ and Thomas et al³⁰ included behavioural therapy interventions yet differed in their usage of antidepressant medication alongside their interventions, leading to difficulty comparing their findings. They also differed in the amount of therapist contact and reported different follow-up periods.

On reading the Alexopoulos et al²⁷ published paper, it would seem that the intervention was more efficacious than the active control group in reducing depressive symptoms from pre- to post-intervention; however the p-value for this calculation did not quite reach significance ($p = 0.054$). Although Alexopoulos et al²⁷, Lincoln and Flannaghan²⁸ and Towle et al³¹ did not find any statistically significant differences between the intervention and control groups in terms of reduction in depression scores over time, these studies did find that participants in both conditions showed a reduction in depression scores over time. While this finding maybe due to spontaneous recovery in depression which may have occurred regardless of the intervention, the size of the samples in these three studies^{27,28,31} were only sufficient to enable power of less than 0.70 (less than 39 participants per condition). Therefore, the sample sizes may have been too small to find a significant

difference between the conditions. Alexopoulos et al²⁷ and Towle et al³¹ did not use a passive control group and it is possible that the control intervention also had a therapeutic benefit on mood, leading to the lack of statistically significant differences between conditions.

1.5.2.2 Samples containing both depressed and non-depressed participants:

Two of the studies which included both depressed and non-depressed participants were calculated to have medium effect sizes for the improvement in depression scores for the intervention group at their respective end points: Chang et al³³ (pre-versus post-intervention) and Clark et al³⁴ (pre-intervention versus one-month follow-up).

When comparing the change in depression scores over time for the intervention and control groups; the improvement in depression scores from pre- to post-intervention was statistically significant for the intervention group when compared to the control groups for Chang et al.³³ Watkins et al⁵ also found a statistically significant difference in the improvement in depression scores between the intervention and control group from pre-intervention to two-month and eleven-month follow-up. Both these studies differed in their methodologies; Watkins et al⁵ investigated a motivational interviewing intervention while Chang et al³³ investigated a novel intervention. These two studies^{5,33} also differed in the amount of therapist contact, length of follow-up periods and statistical analysis used. These methodological differences lead to difficulty comparing these findings.

The remaining nine studies^{32,34-41} did not find statistically significant differences between the intervention and control groups in terms of improvement in depression

scores post-treatment or at follow-up. However, five of these studies^{32,37,38,40,41} did find that participants in both conditions showed a reduction in depression scores over time. While this may be due to spontaneous recovery in depression over time, it may be possible that Aben et al,³² Ostwald et al⁴⁰ and Rochette et al⁴¹ did not find statistically significant differences between conditions because they did not use a passive control group and therefore the control group also had a therapeutic benefit on mood. The size of the samples used by three studies^{34,35,37} were only sufficient to enable power of less than 0.70 (less than 39 participants per condition). Therefore, the sample sizes may have been too small to find a significant difference between the conditions. It seems likely that a depression only sample would have more scope to demonstrate change in depression than mixed population samples; therefore it is possible that these studies did not find statistically significant differences between the conditions because the samples in both conditions contained both depressed and non-depressed participants.

1.5.2.3 Critical appraisal of the evidence that psychosocial interventions are effective in PSD

Overall, four^{5,29,30,33} of the 16 studies found statistically significant improvements in depression scores in the intervention group compared to controls at their reported end points. The sample sizes for three of these studies^{29,30,33} were also relatively small suggesting the significant differences found were not due to large samples being used.

The studies which received the highest methodological ratings^{5,29,30} also found a significant improvement in depression scores in the intervention group compared to

the controls, suggesting that poor design may have been responsible for other studies not finding significant results. However, Chang et al³³ found a significant result despite receiving a lower methodological rating score.

There appears to be some methodological limitations within all four studies^{5,29,30,33} which limit the conclusions which can be drawn from their findings. Chang et al³³ and Thomas et al³⁰ both used outcome measures for depression that were rated by an observer yet the published materials for these studies did not make reference to concealment to allocation, it may therefore be possible that the results of these studies were biased by observers' not being blinded to group allocation. Chang et al³³ did not include a follow-up period and the follow-up period included by Thomas et al³⁰ was relatively short (three-months), limiting the conclusions which can be drawn in terms of the long-term benefits of these interventions. Mitchell et al,²⁹ Thomas et al³⁰ and Watkins et al⁵ all described using intention-to-treat (ITT) analysis although it was unclear in the published material which data they had used to replace missing data and it may have been possible that an inappropriate method was used to replace missing data, creating a bias in their results and leading to a significant difference being found when there was not. Yet, the attrition rates for all these four studies^{5,29,30,33} were relatively small (less than 20% of the total participants), limiting the impact of this methodological limitation. Chang et al,³³ Mitchell et al²⁹ and Thomas et al³⁰ applied inclusion/exclusion criteria which limited the clinical representativeness of the sample; therefore limiting the generalisability of their findings. Only three^{5,28,38} of the 16 included studies addressed the clinical representativeness of the sample well and of these only one demonstrated a significant impact of the intervention over control.⁵

1.6 Discussion

Four of the included studies^{5,29,30,33} found a significant improvement in depression levels in the intervention groups compared to the control groups at their reported end points. High to medium effect sizes were also calculated for these four studies in the intervention groups when comparing pre-intervention to post-intervention and follow-up. These findings differ from the previous Cochrane meta-analysis⁸ which did not find any benefit of psychotherapy for PSD, possibly because the current review included additional recent research and also included a larger number of studies by broadening the inclusion criteria to include samples containing both depressed and non-depressed participants.

While four studies^{5,29,30,33} included in the current review found a significant improvement in depression levels in the intervention groups compared to the control groups, all four studies were found to have methodological limitations which reduce the generalisability of their findings. The remaining 12 included studies did not find any statistically significant differences between the intervention and control groups in terms of improvements in depression scores over time; consistent with the findings of Kneebone and Dunmore¹⁸ and the Cochrane meta-analysis⁸

1.6.1 Methodological Quality and Implications for future research

Methodological strengths of the studies included low attrition rates, appropriate methods of randomisation and appropriate use of depression outcome measures. However, there are a number of methodological problems within the existing literature for psychological interventions for PSD which limit our ability to draw any meaningful conclusions on the effectiveness of psychosocial interventions for PSD.³

The current review identified methodological limitations within the included studies, consistent with the findings of previous reviews.^{8,15,17,18} Studies included in the current review were found to have small sample sizes leading to insufficient power for statistical analysis. They also differed on the amount of time which had elapsed post-stroke, which limits the generalisability of their findings as stage in stroke journey may influence how beneficial participants find a psychosocial intervention. Future research should address these issues by using larger samples to increase the statistical power and also allow for variables within the sample to be controlled for, such as the length of time elapsed since stroke.⁸

Thirteen of the included studies applied inclusion/exclusion criteria which limited the generalisability of their findings. Nine studies excluded participants with communication or cognitive problems, however these are common consequences post-stroke and therefore the samples tended to be selective and not totally representative of clinical populations of stroke patients.⁸ However, it could be argued that in psychotherapy research it is important that participants are able to communicate and have the cognitive ability to engage in the therapy.⁸ Therefore, it is important that future studies get a balance between recruiting an appropriate sample for psychotherapy research against including a clinically relevant sample.

Five^{27,31,32,40,41} of the studies which did not find any statistically significant differences between conditions in terms of improvements in depression scores over time did not use a passive control group. It is possible that the control intervention also had a therapeutic benefit on mood, leading to the lack of statistically significant differences between groups. These findings are consistent with Picton¹⁷ who

recommend that future research should employ multiple treatment designs like that used by Lincoln and Flannaghan²⁸ to permit greater confidence in the reliability and validity of research findings.

To allow researchers to assess maintenance and remission rates following exposure to a psychosocial intervention it is highly important that psychotherapy research uses longer follow-up periods than those used previously.

Overall the information provided by the included studies regarding the interventions and therapist training was poor. The majority of published papers also did not discuss measures of treatment fidelity, consistent with the findings of the previous systematic reviews.^{8,17} The lack of consistency among psychotherapy research in terms of therapist training and adherence to the therapeutic model may have an effect on research findings as intervention efficacy is linked to sufficient exposure to the intervention.⁸ The previous meta-analysis by Cochrane⁸ recommended that future stroke psychotherapy research trials are delivered by therapists trained and supervised in the intervention, using standardised framework of therapy with the use of pre-determined manuals to demonstrate consistency in findings. This information should be detailed in published materials to aid transparency of research. It is possible that the inconsistency we found among studies in terms of the benefit of psychosocial interventions on mood may be explained by the differences in intervention methodologies; there is a need for a more consistent approach to conducting and reporting psychotherapy research post-stroke.

From the findings of their own systematic review, Picton¹⁷ suggested that previous research has not found any benefit of non-pharmacological interventions for PSD

because of methodological limitations within previous research rather than a genuine ineffectiveness of non-pharmacological interventions. The findings of the current review appear to support this.

1.6.2 Implications for clinical practice

Consistent with the findings of Hackett et al⁸ the current review included very few studies of interventions commonly provided in clinical practice such as CBT or counselling¹¹.

Talking-therapies and in particular cognitive-behavioural therapy (CBT) are outlined in a number of clinical guidelines. ‘The Matrix: A guide to delivering evidence-based psychological therapies in Scotland’¹³ ‘recommends’ the use of CBT for PSD and the Scottish Intercollegiate Guidelines Network⁹ have also included talking-based therapies in their clinical practice recommendations for treating PSD. However, the current systematic review has not reliably demonstrated support for these recommendations based on a review of RCT evidence. These recommendations are based on the findings of non-controlled studies and the clinical experience of the guideline development group. Lincoln and Flannaghan’s²⁸ study is referenced in the ‘Psychological Matrix’¹³ as evidence for the use of CBT for PSD; however their study found no significant benefit of CBT for PSD over control groups. There seems to be some unanswered questions over the effectiveness of CBT for PSD with it being suggested that it may be an appropriate intervention for some but not all depressed stroke patients.⁴² Broomfield et al¹ have claimed that CBT should be an effective treatment for PSD and one reason for these mixed results is the failure of clinicians to use an augmented and individually tailored model of CBT. Kootker et

al⁶ recently published a protocol for an RCT investigating the effectiveness of an augmented CBT intervention for PSD; however at the time of conducting this review the findings of this study were not available.

1.6.3 Strengths and limitations of the review

The review was carried out systematically to review all the studies available in the area. The account of the search has been detailed above to allow for transparency. The appraisal of quality for included studies was also conducted systematically. While, the measure of methodological quality used in this review did not allow for exact comparison between studies it did allow us to identify methodological strengths and limitations of the included studies.⁴³

The concept of psychosocial interventions has many different definitions and choosing to use one definition creates a subjective bias, although this decision was taken to increase the transparency of the search process. Open discussions between contributing clinicians were carried out to reduce the subjective bias in identifying papers which met the criteria for a psychosocial intervention.

To limit a possible publication bias we contacted the authors of all the included studies and any identified protocols which may have been relevant for inclusion to incorporate any unpublished findings. The potential bias in methodological quality review was limited by independently rating the quality of included studies and reviewing the degree of inter-rater reliability, which was found to be high.

A further limitation of the current review is that only studies available in English were included. This decision was taken as it was outside the scope of the research to

be able to translate all papers necessary for inclusion. The authors acknowledged that while there are benefits to including papers from across the world, focussing on studies conducted in countries with similar cultures is paramount.

1.7 Conclusions:

The current systematic review investigated the effectiveness of psychosocial interventions on reducing depression scores post-stroke when compared to controls. The methodological quality of included studies was also considered. While the review identified some evidence for the effectiveness of psychosocial interventions in reducing depression post-stroke; this was limited to a very small number of studies and confidence in these findings is limited due to methodological limitations within these studies. Consistent with previous review findings, the review also identified that previous research may not have found any benefit of psychosocial interventions for PSD due to methodological limitations within research rather than a genuine ineffectiveness of the intervention. Therefore, the evidence base is currently insufficient and further research which utilises a robust methodology is needed before any reliable conclusions can be drawn regarding the effectiveness of psychosocial interventions for PSD.

1.8 Clinical Messages

- While the review identified some evidence for the effectiveness of psychosocial interventions in reducing depression post-stroke; this was limited to a very small number of studies and confidence in these findings is limited due to methodological limitations within these studies.
- Future research must address the methodological limitations identified such as: adequate sample sizes, well defined and monitored psychosocial interventions and sufficient follow-up period.

1.9 Acknowledgements

We would like to thank the authors of the reviewed papers and authors of relevant trial protocols for their patience and responses to our email correspondences. Thank you to Rowena Stewart, Liaison Librarian at the University of Edinburgh for her advice regarding electronic database searches.

1.10 Declaration of Interests

This systematic review was conducted as part of a portfolio thesis completed as part of a doctorate in Clinical Psychology undertaken at the University of Edinburgh.

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1.11 Systematic Review Journal Article Appendices

Appendix A: Search strategy used in EMBASE

EMBASE (1980-2013);

- 1 exp cerebrovascular accident, brain infarction/ or infarction, brain ischemia/ or transient ischemic attack, brain haemorrhage, stroke.mp.
- 2 mood.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword], depression.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword], exp depression/ or exp mood disorder/ or late life depression/ or major depression, mood, exp major depression
- 3 exp cognitive therapy, exp psychotherapy/ or exp behavior modification/ or exp behavior therapy/ or exp cognitive behavioral stress management/ or exp cognitive rehabilitation/ or exp cognitive therapy/ or exp family therapy/ or exp group therapy, cognition/ or guided imagery, exp counseling/ or therapy/ or exp directive counseling/ or exp family counseling/ or exp motivational interviewing/ or exp patient counselling, clinical psychology, group therapy, computer assisted therapy, exp psychosocial rehabilitation, mental health service/ or mental health care, social support/ or social care, behavior change, community psychiatric, nursing, social work, psychoanalysis, motivational interviewing, (acceptance and commitment therapy).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword], self help, dialectical behavior therapy.mp., interpersonal psychotherapy.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword], interpersonal therapy.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword], rehabilitation, problem solving, health education/ or education/ or patient education/ or exp psychoeducation, "quality of life", imagery/ or guided imagery, imagery/ or guided imagery, attitude to health
- 4 1 and 2 and 3
- 5 limit 4 to randomized controlled trial

Appendix B: Summary of the studies excluded after reading the full article.

Reason for exclusion	Number of studies
Not a psychosocial intervention	67
Caregiver intervention only	5
Not a randomised controlled trial	5
RCT Protocol only/ no data currently available	6
Large proportion (>10%) of sample experienced a subarachnoid haemorrhage	1
Non-stroke patients/ no separate data available for stroke patients	5
Did not use depression outcome measure	11
Study excluded patients with diagnosis of depression	7
Study unavailable in English	18

2. An investigation into the acceptability and worth of an Interpersonal Psychotherapy assessment and formulation for stroke patients experiencing depression

Journal Format: British Journal of Clinical Psychology

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Word count: 7,893

(Please note British Journal of Clinical Psychology have published three papers with a similar methodology to this empirical study, all of which had a similar word count to this)

2.1 Abstract

Objectives: The evidence base for the use of psychological interventions for post-stroke depression (PSD) is currently insufficient. This study explored participants' experiences of an Interpersonal Psychotherapy (IPT) assessment and formulation post-stroke to investigate the acceptability of using this model with patients experiencing PSD and indicate if more detailed quantitative research is justified.

Methods: Ten participants with PSD received two IPT assessment appointments with a Clinical Psychologist, generating an IPT formulation of their difficulties. Participants subsequently took part in a semi-structured interview about their experience of this process. The results of these interviews were transcribed and analysed using Framework Analysis.

Results: Participants were seen to link their difficulties post-stroke to three of the four IPT interpersonal focus areas; interpersonal disputes, role transitions and grief loss. Overall, participants found an IPT assessment and formulation to be acceptable and identified benefits of the sessions including: altering their viewpoint, increasing acceptance of impaired functioning, reducing frustration, increasing positive feelings and leading to improvements in their social support. While participants recognised that lasting advantages in terms of mood were limited, this reflected the time-limited nature of the intervention participants received.

Conclusions: IPT may therefore be a suitable intervention for PSD and further robust, quantitative research is justifiable. Results suggest acceptance and an altered viewpoint are common following an IPT assessment and formulation; therefore

future IPT research should measure changes in these variables alongside mood and behaviour.

2.2 Practitioner Points:

- Participants within the current study were seen to link post-stroke depression with interpersonal difficulties. Participants found an Interpersonal Psychotherapy (IPT) assessment and formulation of their low mood post-stroke to be acceptable.
- Participants suggested benefits of the IPT assessment and formulation such as: altering their point of view, recognising the impact of their stroke on others, increasing acceptance of impaired functioning, reducing frustration, increasing positive feelings and leading to improvements in their social support.
- This was a single site study which explored a lived experience of individuals with a unique experience.
- The sample size used was relatively small; however the sample was reasonably homogenous, increasing the potential to identify reliable findings within a relatively small sample.

2.3 Introduction

Approximately one third of all stroke patients experience depression; correlates of post-stroke depression (PSD) include: reduced quality of life, delayed functional recovery, increased cognitive impairment, increased health care usage, increased social isolation and increased risk of mortality (Broomfield *et al.*, 2011; Gillespie, Joice, Lawrence & Whittick, 2011; Salter, Foley & Teasell, 2010; Watkins *et al.*, 2011).

Antidepressant medication has been found to be an effective treatment for PSD, although research suggests that this treatment should be used with caution and reserved for patients with severe and persistent depressive disorder due to the associated side effects (Hackett, Anderson, House & Xia, 2008; NHS Improvement-Stroke, 2010). Psychological interventions have been found to be effective treatments for depression in non-stroke populations including working-aged adults, older adults, chronically depressed patients and patients with subthreshold depression (Cuijpers, Andersson, Donker & van Straten, 2011). However, psychological interventions for PSD have received little investigation (Kootker, Fasotti, Rasquin, van Heugten & Geurts, 2012). A recent systematic review conducted by Cathers, Morris and Platten (unpublished) reported that the evidence for the effectiveness of psychosocial interventions on improving mood post-stroke remains insufficient partially due to methodological limitations within studies such as: inappropriate follow-up periods, inadequate sample sizes, poor definition of the intervention and lack of measures used to assess treatment fidelity. This suggests there is a need for further, robust research in this area.

2.3.1 Interpersonal Psychotherapy

Interpersonal Psychotherapy (IPT) is a short-term (12-16 sessions) intervention which is built on the principle that a person's interpersonal distress is linked to their psychological symptoms (Klerman, Weissman, Rounsaville & Chevron, 1984; Stuart & Robertson, 2003). The intervention aims to improve patients' communication and social support by focusing on conflicts and transitions in their existing relationships and helping them build and utilise their existing support network (Stuart & Robertson, 2003). IPT links patients' mood to one of four interpersonal problem areas: grief and loss, interpersonal disputes, role transitions or interpersonal sensitivity (Klerman *et al.*, 1984). The grief focus was traditionally only used when there had been a death (Klerman *et al.*, 1984). However, more recently it has been proposed that the grief focus can be used to formulate non-bereavement losses such as a divorce, illness or unemployment (Stuart & Robertson, 2003). The different stages of an IPT intervention are shown in Table 1.

IPT has been found to be an efficacious treatment for depression in non-stroke populations, both independently and in combination with pharmacotherapy (Cuijpers, Geraedts *et al.*, 2011). The National Institute for Health and Clinical Excellence (2010) and the Scottish Intercollegiate Guidelines Network (2010) recommend the use of IPT for depression in adults. 'The Matrix: A guide to delivering evidence-based psychological therapies in Scotland' (The Scottish Government & NHS Education Scotland, 2011) also recommends the use of IPT as a treatment for depression in adolescents, working-aged adults and as a maintenance treatment in older adults.

Table 1: ‘The components of IPT’ (based on Stuart & Robertson, 2003; Table 3.1; P39)

<i>Initial Sessions (sessions 1-2)</i>	<p>Fully assess psychiatric and interpersonal problems.</p> <p>Develop an interpersonal formulation</p> <p>Complete IPT inventory: listing patients’ key relationships and problems associated with them.</p> <p>Identify problem area (<i>grief and loss, disputes, role transitions or interpersonal sensitivity</i>).</p> <p>Explain the purpose and rationale for IPT</p> <p>Establish a contract which details expectations for treatment.</p>
<i>Middle Sessions (sessions 3-12)</i>	<p>Attend to therapeutic relationship, maintain focus on problem area, explore patient’s expectations of relationships and use problem solving and other techniques</p>
<i>Conclusion of acute treatment (sessions 13-14)</i>	<p>Patient’s progress is reviewed and future difficulties are anticipated. Patient’s gains are reinforced</p>
<i>Maintenance Treatment (sessions 15+)</i>	<p>Maintenance contract is developed and relapse prevention techniques used.</p>

There are several reasons to hypothesise that IPT will be an appropriate intervention for PSD. Guidelines suggest that IPT is an appropriate treatment option when distress can be linked to one of the four interpersonal problem areas (grief and loss, disputes, role transitions or interpersonal sensitivity). These interpersonal problem areas have emerged as themes within the exiting post-stroke literature suggesting that distress post-stroke could be linked to these interpersonal problem areas. Salter, Helling, Foley and Teasell (2008) carried out a meta-synthesis of nine qualitative studies to investigate patients’ experiences post-stroke. A dominant theme of “*change, transition and transformation*” was identified, where patients experienced stroke as a sudden and catastrophic life event which impacted on personality, roles, social relationships and abilities. Other themes identified included: “*loss*”; “*uncertainty*” and “*social isolation*”, which also seem to fit with the principles of IPT. Social

support, which IPT aims to improve, has also been found to be protective in relation to the onset and course of depressed mood post-stroke (Hilari *et al.*, 2010; Salter *et al.*, 2010).

Finkenzeller, Zibel, Rietz, Schramm and Berger (2009) conducted a randomised controlled trial investigating the effectiveness of three different treatments for PSD: IPT, Pharmacotherapy and IPT plus Pharmacotherapy. In all three treatment groups depression levels significantly reduced over time. However, no statistically significant differences between the treatment groups were found in terms of patients' mood. Methodological limitations, such as use of active comparison groups and a relatively small sample, may explain why a significant difference between treatment groups was not found. The authors concluded that all three treatments were effective in reducing PSD and further research is needed into the use of IPT for PSD to address the methodological limitations of their study.

2.3.2 Qualitative Enquiry

Outcome research is dominated by quantitative measures, investigating the effectiveness of an intervention in reducing psychological distress (Williams, McManus, Muse & Williams, 2011). However, this is often at the cost of gaining an in-depth understanding of personal experiences (Messari & Hallam, 2003). Qualitative information can aid our understanding of outcomes research and directly influence the efficacy and cost-effectiveness of future interventions (Williams *et al.*, 2011). Qualitative analysis is often appropriate to investigate the suitability and likely efficacy of an intervention to indicate whether more detailed and expensive quantitative trial research is justifiable (Smith, Graham & Senthinathan, 2007).

Previous qualitative research has explored participants' experiences of various psychosocial interventions, including cognitive therapy for social phobia (McManus, Peerbhoy, Larkin & Clark, 2010), cognitive-behavioural therapy (CBT) for psychosis (Messari & Hallam, 2003), and mindfulness-based cognitive therapy (Finucane & Mercer, 2006; Mason & Hargreaves, 2001; Smith *et al.*, 2007; Williams *et al.*, 2011).

Due to time and clinical constraints it was not possible to provide participants in the current study with a full 16-week intervention. The current study therefore aimed to explore the acceptability of an IPT assessment and formulation of PSD difficulties, with patients receiving two sessions to introduce them to the IPT model and give them a sense of what an IPT intervention would entail. The current study used a similar methodology to that used by Pain, Chadwick and Abba (2008) to investigate patients' experiences of case formulation in CBT for psychosis.

2.4 Research Questions

1. How acceptable is an IPT assessment and formulation of difficulties for stroke patients experiencing depression?
2. What are the advantages of an IPT assessment and formulation for stroke patients experiencing depression?
3. What are the disadvantages of an IPT assessment and formulation for stroke patients experiencing depression?

2.5 Method

2.5.1 Ethical review

Full ethical approval was given by the West of Scotland Research Ethics Service and the local NHS' Research and Development Department.

2.5.2 Participants

Potential participants were identified by the Stroke Liaison Nurses (SLN) and the Clinical Psychologist attached to the stroke service, who reviewed their database of all stroke patients in the region using the inclusion and exclusion criteria (Table 2). Recruitment packs were sent out in small batches to limit the number of patients contacted but not subsequently asked to take part in the study. Recruitment packs contained a letter inviting potential participants to take part, a participant information sheet, an opt-in slip and a stamped addressed envelope.

Table 2: Inclusion and exclusion criteria used

Inclusion criteria
Scored eight or above on the Hospital Anxiety and Depression Scale-Depression subscale
Scored 23 or above on the Montreal Cognitive Assessment
Physically able to provide written responses
Aged 18 or over
Experienced either an ischemic or haemorrhagic stroke within the last four years
At least one month post-discharge from an acute hospital
Exclusion Criteria
Unable to complete sessions due to severe aphasia, hemiplegia, hemiparesis or ataxia
Unable to speak English
History of drug abuse
History of severe and enduring mental health problems
Experienced stroke in childhood

Those who expressed an interest in taking part were telephoned by the researcher; an assessment appointment was then arranged at a location of the patient's choice to further determine their suitability using the inclusion and exclusion criteria. Informed written consent was gained at the assessment appointment for all participants who met the criteria. Participants' General Practitioners (GPs) were informed in writing of the participant's involvement in the study.

Recruitment packs were sent out to 40 stroke patients between December 2012 and November 2013. Opt-in slips were received from sixteen potential participants, of which four did not meet the inclusion criteria at assessment, one did not provide consent to participate and one withdrew from the study prior to their first planned IPT session. The remaining ten participants attended both of the IPT sessions and the interview; their details are provided in Table 3.

Table 3: Participant characteristics

Participant Number	Gender	*Age (at consent)	Months since stroke (at consent)	Hospital Anxiety and Depression Scale- Depression Subscale (HADS-D)		Hospital Anxiety and Depression Scale- Anxiety Subscale (HADS-A)		Montreal Cognitive Assessment (MoCA) (at consent)	Multi- dimensional Scale of Perceived Social Support (MSPSS) (at consent)	Fatigue Assessment Scale (FA) (at consent)
				at consent	at interview	at consent	at interview			
P1	F	60s	31	9	3	6	6	27	7.00	26
P2	M	50s	15	16	9	9	5	25	5.66	33
P3	F	70s	8	10	3	3	4	23	4.16	21
P4	M	60s	12	10	6	12	12	28	4.42	27
P5	F	80s	6	8	9	9	11	27	4.50	33
P6	F	30s	12	14	8	12	11	27	1.83	30
P7	M	60s	39	14	10	17	17	25	3.08	35
P8	M	40s	32	15	15	17	11	27	1.42	23
P9	F	70s	35	9	9	9	8	27	2.50	32
P10	F	60s	40	9	6	12	9	27	5.58	28

**the exact age of participants has been removed to maintain confidentiality.*

2.5.3 Measures

Measures were included to ensure that participants met the studies' inclusion criteria and to describe the sample in terms of anxiety levels, fatigue levels and perceived social support. These measures were not quantitatively analysed.

Participants completed the *Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith 1983)* prior to the IPT sessions and during the semi-structured interview. The HADS consists of two 7-item subscales: anxiety subscale (HADS-A) and the depression subscale (HADS-D) (Bjelland, Dahl, Haug & Neckelmann, 2002). For each subscale the total score is out of 21, higher scores are indicative of greater levels of anxiety and depression (Flint & Rifat, 2002). The HADS was specifically developed for patients with somatic comorbidity and demonstrates good psychometric properties with post-stroke patients (Aben, Verhey, Lousberg, Lodder & Honig, 2002; Zigmond & Snaith 1983).

To ensure that all participants had the cognitive abilities necessary to take part in the study *The Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005)* was completed during the assessment appointment.

Participants also completed the *Fatigue Assessment Scale (FAS; Michielsen, De Vries & Van Heck, 2003)* and *The Multidimensional Scale of Perceived Social Support (MSPSS; Zimet, Dahlem, Zimet & Farley, 1988)* prior to the IPT sessions.

2.5.4 IPT Assessment and Formulation

Each participant received two IPT sessions, each approximately one hour long; held two weeks apart at a location of the participant's choice. The aim of these sessions

was to carry out an assessment and formulation of the participant's difficulties using an IPT model. The content of these sessions followed a structured protocol devised by the researchers following published guidance on IPT assessment and formulation (Klerman *et al.*, 1984; Stuart & Robertson, 2003). The protocol was reviewed by members of the academic team at the University of Edinburgh and practitioners accredited in the use of IPT. The session protocol initially introduced participants to the "sick role" and looked at the impact their stroke had had on them and their mood. The interpersonal inventory was then completed for a maximum of six people who the participants felt were important to them. Finally, an IPT formulation of the participant's current difficulties was completed collaboratively using a formulation template (Figure 1) which underwent the same design process as the session protocol. Approximately one week after their last IPT appointment all participants received a written formulation of their difficulties in the post; a copy was also sent to their GP.

The two IPT sessions were conducted by the Clinical Psychologist attached to the stroke service. Although she was not formally accredited in the use of IPT, she had received three days training on using the model. She followed a structured protocol and was supervised closely by a Clinical Psychologist accredited in the use of IPT. All IPT sessions were audio recorded. The audio recordings of five randomly selected sessions were rated by a Clinical Psychologist accredited in the use of IPT for IPT quality assurance. A copy of the session protocol can be obtained from the first author.

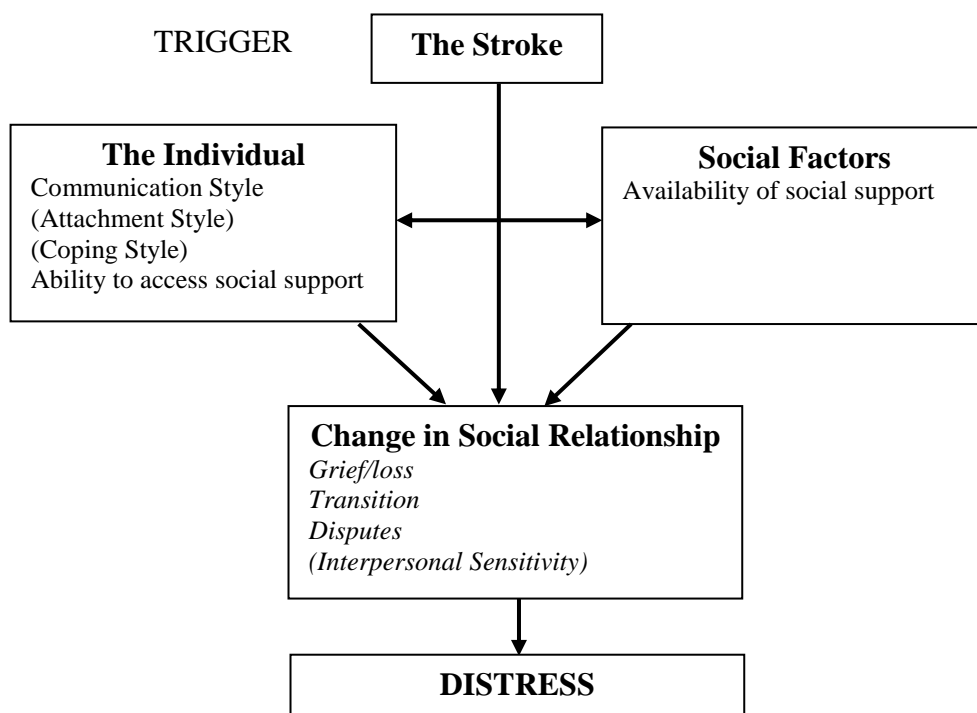


Figure 1: Formulation template used

2.5.5 Semi-structured Interview:

Three weeks after their final IPT session participants took part in a one-to-one semi-structured. A standard interview schedule was developed by researchers after reviewing the guidance by Ritchie and Spencer (2003) and also reviewing topics covered by previous research exploring patients' experiences of psychotherapy (Finucane & Mercer, 2006; Mason & Hargreaves, 2001; McManus *et al.*, 2010; Messari & Hallam, 2003; Smith *et al.*, 2007; Williams *et al.*, 2011). Researchers at the University of Edinburgh were consulted for their thoughts on the interview schedule and practice interviews were conducted with a layperson. The interview, which covered topics detailed in Table 4, followed a relaxed interview style (Finucane & Mercer, 2006). Questions were open-ended, e.g. "Tell me how you felt about your two sessions", with cues and prompts used to gather detail, e.g. "Was

there anything you found useful about these sessions?” (Srivastava & Thomson, 2009). Summaries and reflections were used to elicit more detail and check participants’ experiences were being correctly interpreted (Pain *et al.*, 2008). The interviews all opened with a standard introduction concerning the aims and structure of the interview. All interviews closed with participants being offered the opportunity to add further information.

The authors were aware of the potential bias of the researcher being associated with the Psychology service as part of her work component. Participants were therefore reassured that the interviews were confidential. Interviews were also held at a location of the participant’s choice. Throughout the interviews participants were encouraged to raise negatives opinions as well as positive opinions.

Interviews were audio-recorded with participants’ consent and lasted between 25.2 and 61.3 mins (mean = 42.5 min; Standard deviation = 9.1). All audio recordings were transcribed, removing any information which would identify participants to ensure complete anonymity. Audio recordings were checked against transcripts for accuracy.

Table 4: Interview schedule used

1. How participants felt about the two IPT sessions. (Helpful and unhelpful aspects of therapy)
2. Their thoughts on the formulation and assessment.
3. Impact of the sessions.
4. What would they tell someone who was just about to start the IPT sessions.
5. Ways to improve the sessions.
6. Comparing IPT to other models of therapy.
7. Their thoughts on further IPT sessions.

2.5.6 Qualitative data analysis

Previous research investigating patients' experiences of psychotherapy have used a variety of different qualitative research methods including: thematic analysis (Smith *et al.*, 2007), interpretative phenomenological analysis (McManus *et al.*, 2010; Williams *et al.*, 2011), framework analysis (Finucane & Mercer, 2006), discourse analysis (Messari & Hallam, 2003), content analysis (Pain *et al.*, 2008) and grounded theory (Mason & Hargreaves, 2001). The current study was not specifically interested in how individuals made sense of their experiences and did not hope to generate a theory from the data; therefore the use of phenomenological or grounded theory approaches were not felt to be appropriate. Framework analysis (FA) (Ritchie & Spencer, 1994) was used to analyse the transcripts. FA is grounded in the data and is a dynamic and systematic method (Ritchie & Spencer, 1994; Srivastava & Thomson, 2009). FA was selected as it allows analysts to move between the dynamic stages, leading to transparency in the themes and adding rigour and validity (Ritchie & Lewis, 2003; Smith & Firth, 2011). FA also allows participants' views to be considered collectively while also allowing individuals' perspectives to be analysed separately, which was felt to be important for this particular study (Smith & Firth, 2011). The study followed the five dynamic stages of FA (Ritchie & Spencer, 1994):

- 1. Familiarisation:** all audio recordings were transcribed before repeatedly reading through each transcript. Recurring ideas and themes within the data were noted.
- 2. Identifying a thematic framework:** The list of ideas and themes within the data was used to generate a thematic framework consisting of main themes with a series of subthemes. This thematic framework was applied to the raw data; it was

continually refined during this process creating six different versions of the thematic framework.

3. Indexing: The final version (version 6, see Appendix) of the thematic framework was then applied to the full data set. Each sentence from participants' narratives was indexed by theme.

4. Charting: The indexed quotes were then summarised, synthesised and sorted by theme and participant into a thematic chart. This was done using computerised spreadsheet software. Participants' language was retained where possible during this process.

5. Mapping and interpretation: During this stage, the thematic charts were used to develop associations and patterns within themes. The researcher spent time interpreting and seeking wider application for the identified themes (Smith & Frith, 2011).

2.5.6.1 Validity

The authors consulted guidelines for enhancing the validity of qualitative research when planning and carrying out this study (Yardley, 2008; Ritchie & Lewis, 2003). The researcher was aware of the potential subjectivity that researchers bring to all methods of qualitative analysis. The researcher therefore continuously returned to the raw data during analysis and the themes identified closely retained the language used by participants. The second researcher was consulted frequently throughout analysis to discuss emerging themes, potential index refinement and ways to display the data (Yardley, 2008), reducing any possible subjective bias in results. FA allows analysts

to move between the dynamic stages, leading to transparency in the themes (Ritchie & Lewis, 2003).

Efforts were made to be open to new themes or examples which contradicted the developing understanding.

2.6 Results

Four key themes were identified: ‘acknowledging the therapeutic alliance’, ‘reflections on practical aspects of an IPT assessment and formulation’, ‘reactions to an IPT assessment and formulation’ and ‘realisations and recognitions following the IPT assessment and formulation’. A fifth set of index categories were grouped together to capture aspects of the data which focussed on participants’ ‘recounting experiences of stroke’, which were present in all participants’ interviews. Further index categories were grouped together under ‘describing life events’ and ‘voicing fears’ although not all participants made reference to these categories.

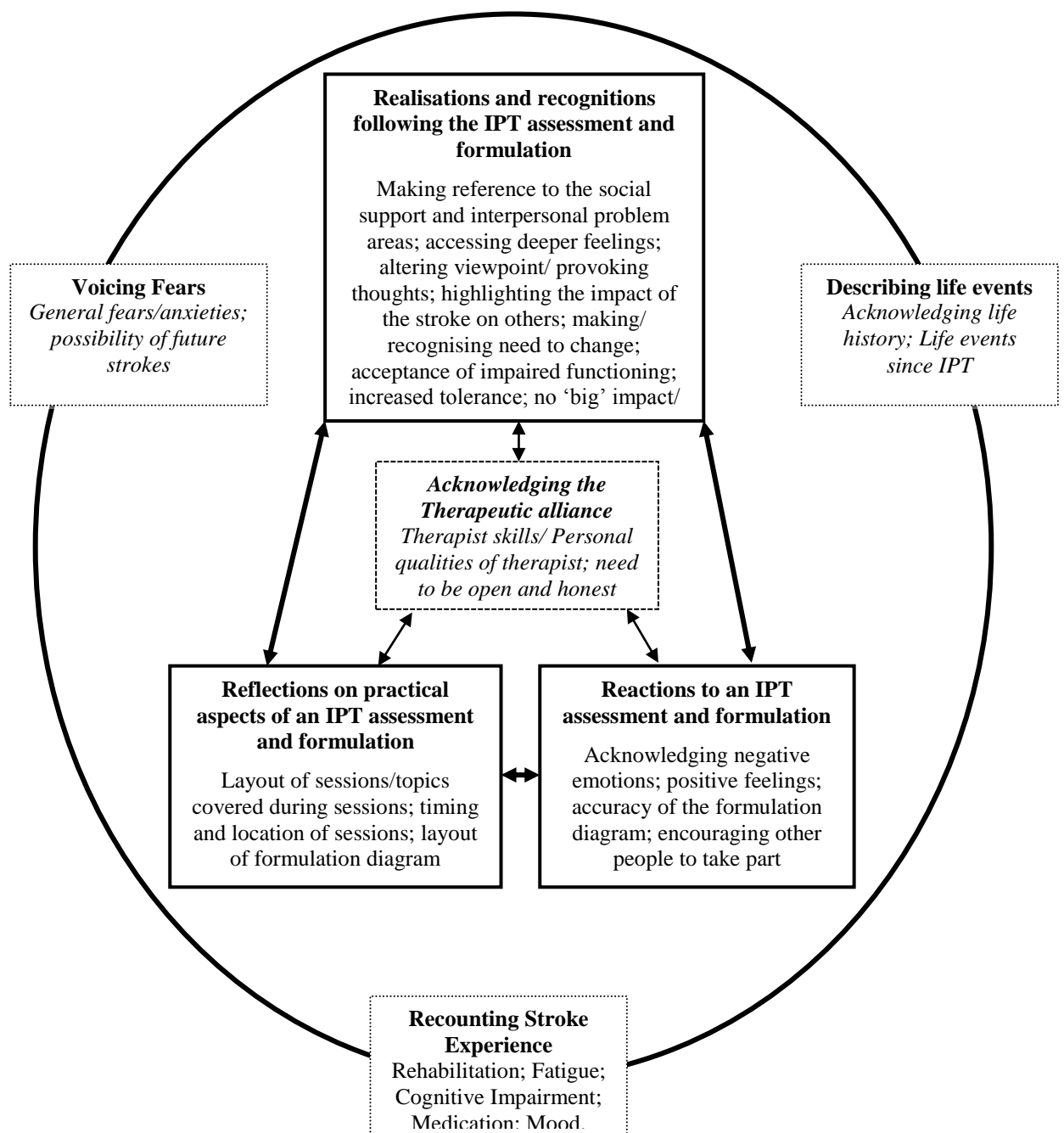


Figure 2: Visual representation of themes generated.

In the following sections each key theme will be explored, commenting on individuals' narratives.

2.6.1 Acknowledging the Therapeutic alliance

Topics within this theme centred around two main areas: a) therapist skills/ personal qualities of the therapist and b) being open and honest

2.6.1.1 Therapist Skills/Personal Qualities of the Therapist.

The majority of participants discussed the personal qualities of the therapist. Participants described the therapist as pleasant, relaxed, friendly and professional; acknowledging that they found it easy to talk to her. Five of participants touched on her professional training.

P5:

I found her personality erm, sort of erm friendly in the professional way. And erm that I liked her, erm (pause), because I didn't, I didn't feel that it was in any way intrusive, in that she sort of erm by the very nature and the, the way of talking freed me to be quite erm open in lots of areas that it was not a difficulty, she didn't, she didn't cause me to have any inhibitions at all and that's very valuable.

The majority of participants acknowledged that they had been able to open up about very personal issues to someone who was practically a stranger to them. The participants described the benefits of talking to someone who was impartial and was outside of their family unit.

P6:

It's the first time outside of any family, anybody that I've been able to speak that's been actually about me.

2.6.1.2 Need to be open and honest

Participants were aware of the importance of them being open and honest during the assessment. They acknowledged the benefits of not going in with a set agenda, or a preconceived idea of things they did not want to talk about; participants instead stressed the importance of being free to talk about whatever came up.

P1:

I felt very free to talk about anything, and to me it felt the same, cos I don't believe in coming to these sessions with a pre-idea I'm not going to this or I'm not going to tell that. Because, your answers, my responses just come out of the questions, and you can't pre-plan what you're going to say. And then that's what, probably that's what's quite good and led to me opening up.

2.6.2 Reflections on practical aspects of an IPT assessment and formulation

During the interviews all participants reflected on their experiences of an IPT assessment and formulation; acknowledging therapeutic aspects which are specific to this model.

2.6.2.1 Layout of sessions/topics covered in an IPT assessment and formulation

Throughout the interviews participants made numerous references to what they had discussed during the assessment. Participants explained that they did not find the

content of the sessions “*threatening*” and “*found it easy to talk about relationships*”. P10 explained that initially she was surprised that she was talking about other people, although it quickly became clear why she was. The majority of participants commented that they found the assessment and formulation was well structured, which they liked. It was acknowledged that the sessions went by very quickly and were very “*full*” sessions.

P9:

it was a professional, straight forward, easy conversation with a purpose, it wasn't just a blather which gets you nowhere, and it was well structured and I felt that at the end of it that it was certainly worthwhile.

P9 went on to suggest that it may have been beneficial to have had someone else with her during the sessions:

P9:

it made me realise that what has happened to me has impacted on other people in the family, which is why I would suggest that, a family approach to this would be helpful.

2.6.2.2 Layout of the IPT formulation diagram

P3 did not comment on the formulation diagram specifically and could not recall details of the formulation when prompted. P6 explained that she had not yet had a chance to look at the completed diagram in detail. The remaining eight participants described the layout of the formulation very positively, acknowledging the benefits of having a chart as opposed to a long report. Participants linked this to the cognitive

changes they have experienced post-stroke and acknowledged that providing information in diagram form with bullet points was useful.

P7:

you know that [points to different document] I'd have to read through it and by the time I got to the end of it I'd have forgotten what was at the beginning of it but that [points to formulation diagram], I can look at it and its little box and I can read in the box and I can go look at the end of it and it's all in a box and I seem to remember things in boxes.

P8:

cos bullet points are absolutely brilliant for me, it makes sense to me,

2.6.3 Reactions to an IPT assessment and formulation

The topics within this theme centred around four main areas: acknowledging negative feelings, leaving with positive feelings, the accuracy of the formulation and encouraging other people to try IPT.

2.6.3.1 Acknowledging negative feelings

Two of the participants [P3 & P10] noted that the assessment and formulation had evoked some negative emotions for them including: guilt, anxiety and frustration at being unable to identify new hobbies.

P10:

you kind of feel a wee bit, treacherous, treat, treacherous, (laughs) erm, saying these kind of things when somebody has been supportive and you know, so (pause), I

suppose that's, kind of where the guilt comes in, because you causing other people anxiety.

P10 noted that the assessment and formulation forced her to look at things she may not have wanted to which she found “*uncomfortable*”. P3 found the sessions very tiring commenting that they did “*drain me completely*”.

2.6.3.2 Leaving with positive feelings:

All the participants made references to the range of positive feelings that they were left with following the IPT assessment and formulation including feeling: free, uplifted, relaxed, more confident, liberated, stimulated, less anxious and lucky to have social supports. It was also noted that the sessions had taken away feelings of isolation and one participant felt they had cried less since the sessions. Participants described the sessions to be pleasant and feeling that they had helped.

P10:

afterwards as I was driving away from it and I was thinking about it, and you know I was kind of going over it and I thought about there was a lot of positive stuff that had come out and then, and I think it did kind of make me realise that you know I am quite fortunate and should focus more on that than the other stuff.

2.6.3.3 Accuracy of the formulation diagram

Participants reported being very surprised by the IPT formulation and how it appeared to capture all the information. The majority of participants talked about the accuracy of the formulation and feeling they knew all the information which it contained.

P1:

I read it and I thought she'd got it absolutely spot on, these were exactly the issues that we, there were no surprises there, it was exactly what it was.

2.6.3.4 Encouraging others to take part

The majority of participants encouraged other people to take part in these sessions, commenting that they had found them worthwhile and beneficial.

P6:

I would advise anybody just to try it because you're not going to lose nothing.

2.6.4 Realisations and recognitions following the IPT assessment and formulation.

Within this theme participants' comments fall within seven different subheadings:

2.6.4.1 Making reference to the social support and interpersonal problem areas

As participants talked about the topics which they had discussed during the two sessions, they made frequent references to their support network.

P1:

I discussed my son and daughter in the sense that they give me a lot of support, and they're quite firm with me when they have to be and that's quite a lot of the time.

During the interviews participants also frequently made reference to interpersonal disputes, role transitions and losses they have experienced post-stroke (IPT interpersonal problem areas).

P8:

it identified the loss that I knows there, I know the loss is there and wasnae dealing with, I've not been dealing with that loss, the loss of the work, the loss of the kids, the car and everything.

P9:

there are lots of things my husband doesn't understand about my situation, or refuses to understand, and I don't want to hurt him by saying, listen, you've got to change your point of view.

P10:

it help to clarify the stroke, things about me, how I was before, the changes that have happened since the stroke and how things, how my role had changed

2.6.4.2 Accessing deeper feelings than other models

Five participants had previous experience of receiving cognitive-behavioural therapy (CBT) interventions. One participant had previous experience of receiving a self-help CBT intervention while one participant had previous experience of receiving a counselling intervention. Five participants had experience of counselling techniques or family therapy interventions as part of their previous occupations. When comparing their experience of IPT to their previous experience of other therapeutic models the majority of participants commented that IPT accessed deeper feelings than other models.

P4:

in depth more, you know. Yeah she seemed to be in-depth more than what I've felt before.

2.6.4.3 The IPT assessment and formulation altered participants' viewpoints and provoked thought

Participants frequently stated that the IPT assessment and formulation had provoked thought. Participants explained that the assessment and formulation had helped them to make connections between things they had not been aware of before such as linking their mood to interpersonal changes which had occurred post-stroke.

P2:

it probably just made thing click er, (pause) a can see how such and such is related to such and such and such and that can affect that and do this, so I think it just clarifies in my mind that everything is in, connected.

It was frequently discussed that the IPT assessment and formulation had highlighted issues that participants may not have been fully aware of before the sessions. Participants also discussed how the sessions had reinforced and confirmed things that they were already aware of.

P6:

I knew where there was issues maybe and things like that but once, once you actually start talking about it does, you're more aware of it again and you're like yeah I suppose things are quite hard

Frequent reference was also made to the fact that the IPT assessment and formulation made participants recognise the impact that their stroke had had on their family and friends.

P4:

being able to talk to her [the therapist] and being able to look at things erm like erm, the way my daughters feel about things... it has really helped erm erm like I hadn't really looked at the way my daughters feel or things, in was in sort of the back of my head but I hadn't really looked at it until we started talking.

2.6.4.4 Acceptance of impaired functioning

Participants frequently acknowledged changes in their functioning post-stroke. During the interviews participants discussed how the IPT assessment and formulation had helped them to accept these changes in their functioning.

P2:

I think speaking to [the therapist] I could see (pause) that I'm having to depend a lot on other people. Er and I probably wasn't wanting to depend, just accepting well they can help me er they can open out. (pause) Ah I'm not sort of relying on myself to do things, I've got to be a wee bit more open and let other people, let other people in.

2.6.4.5 Increased tolerance

Participants also made reference to a reduction in their frustration and increase in their perceived tolerance following the IPT assessment and formulation, which they linked to this perceived shift in their viewpoint.

P6:

I kinda keep telling myself that actually I shouldnae, if I have a bad day, I've not done nothing, dunnae beat myself up cos theres nae point, it's already happened now

2.6.4.6 Making/recognising the need to make changes

Participants made reference to behavioural changes they either had made following the sessions or behavioural changes they recognised they should make. These behavioural changes included making improvements to their social support by increasing communication and being more open and increasing their activity levels. Participants also recognised the importance of allowing more time for themselves and recognising the need to identify current capabilities. The narratives within this theme were heavily linked to participants accepting their current functioning.

P10:

I am more aware about trying to make an effort to keep in touch and, and you know I phoned one of my ex colleagues yesterday and I had a good chat with her so, erm, I think I will make an effort because I think it is too easy,

2.6.4.7 No “big impact”/slipping back

All participants at some point in their narratives commented that the assessment and formulation had either not had any “big” or lasting impact on them or that things had “slipped back” to the way they were before the sessions. Some participants acknowledged the benefits they had taken from the IPT assessment and formulation but commented that the sessions had not really changed anything for them.

P2:

I don't think it has any big impact, a just, (pause), a just feel that the one main thing is that more open. I cannae think of any big impact.

2.6.5 Exploring differences across the sample:

The narratives of the four participants who were below the age of 65 at the time of their stroke appeared to focus more on role transitions post-stroke than the narratives of the older participants. This is possibly because these younger participants were working at the time of their stroke and the stroke impacted on their ability to return to work. One of the participants had dependent children at the time of her stroke and this was reflected quite heavily in her narrative in terms of changes to her parenting role. The semi-structured interview took place during the school holidays which may have influenced her account of the sessions and the perceived impact of the IPT assessment and formulation. This participant commented that she was unable to think about the assessment and formulation after the sessions due to her childcare responsibilities; noting that her mood had dipped during the school holidays.

Further evidence was found across participants' narratives for this link between things 'slipping back' after the two sessions and life events which occurred since the sessions. The HADS-D scores of six participants [P2, P5, P6, P7, P8 & P9] remained within the clinical range (score of eight or over) following the IPT sessions (see Table 3). The narratives of these participants acknowledged that after the IPT sessions they had experienced life events such as physical health problems, interpersonal disputes or work-related stress. Participants acknowledged that these life events may have impacted negatively on their mood. At interview, four

participants [P1, P3, P4 & P10] no longer scored within the clinical range for depression. The narratives of these four participants differed from participants who remained within the clinical range as they did not report any stressful or significant events following the sessions.

One participant [P3] did not identify any benefit from the IPT assessment or formulation, other than it was *“pleasant”*. She did not link the lack of perceived impact of the sessions to any life events but instead commented that it was because she was no longer depressed during the sessions *“I mean I’m not depressed (pause), haven’t been depressed for quite a long time”*. The narrative provided by P3 was very different to that of the other nine participants in that it was short and very few details of the assessment and formulation were discussed, possibly because she did not feel any benefit of the sessions. P3 scored lower on the Montreal Cognitive Assessment (MoCA) than other participants, which may have impacted on her narrative and her ability to recall the sessions.

P7 commented that the benefits he felt immediately after the sessions had gone because he was unable to recall any details of the sessions due to his poor memory *“they were very helpful in that that they made me aware of what was wrong but I’ve forgotten all about them”*. While all participants to some degree commented on changes to their cognitive functioning, P7 heavily referenced his perceived memory difficulties. His apparent memory difficulties also impacted on his narrative as he frequently lost his train of thought.

While all participants commented on their support networks, the narratives of participants who scored low on the Multidimensional Scale of Perceived Social

Support (MSPSS) [P6, P8 & P9] tended to focus more heavily on interpersonal disputes within their social networks and acknowledged a lack of available social support. Participants who scored highly on the MSPSS [P1, P2 & P10] acknowledged that they had good, available social support and commented that they were “*lucky*” to have a good support network.

Two of the participants provided care for a family member and both of these participants commented on the changes which had occurred within this role following their stroke. These two participants both noted that the IPT assessment and formulation had reduced the frustrations they sometimes felt towards the person they care for by helping them to see the other person’s viewpoint.

Three participants discussed their fears that they would have another stroke. For two participants these fears were mentioned briefly in their narratives. However, one participant frequently returned to these worries and their desire to further understand the underlying neurology of their stroke. Further worries discussed by other participants included worries related to a family member’s ill health and worries that people would not believe they have a disability. P7 and P8 both scored highly (17) on the anxiety subscale of the HADS prior to the IPT sessions. However this was not reflected strongly within their interviews possibly because the focus of the IPT assessment and formulation was on low mood and interpersonal issues rather than anxiety.

Throughout the narratives participants described aspects of their life history, the amount of detail they provided and the context in which they shared aspects of their personal histories differed among participants. One participant [P5] offered a

credible reason why participants shared details of their personal history during the interviews:

“it was really inevitable, if you’re going to be whole heartily open, that potentially painful areas of your past, many years pre-stroke would come up and that er probably in her view [the therapist] be quite relevant”

2.7 Discussion

2.7.1 Summary of findings in relation to research questions.

2.7.1.1 How acceptable is an IPT assessment and formulation of difficulties for stroke patients experiencing depression?

Participants reported that the content of the sessions and talking about relationships was beneficial. The majority of participants felt that the IPT formulation was an accurate account of what was going on; suggesting an IPT assessment and formulation is consistent with patients’ difficulties post-stroke. Participants found being given a copy of the formulation valuable and liked the format in which the formulation was presented. Therefore, the results suggest that participants found an IPT assessment and formulation of their difficulties post-stroke to be acceptable. Across the data set participants made reference to encouraging others to take part in the sessions, strengthening the conclusion that the majority of participants found an IPT formulation to be acceptable and beneficial to them.

2.7.1.2 What are the advantages of an IPT assessment and formulation for stroke patients experiencing depression?

Participants made frequent references to a large array of positive feelings they experienced following the IPT assessment and formulation including feeling uplifted, relaxed, more confident, feeling lucky to have social supports, liberated, stimulated, less anxious and less isolated. Other advantages of the sessions which participants noted included: highlighting things they may not have been consciously aware of and reinforcing things they already knew. Participants commented that an IPT model allowed them to access deeper feelings than other models had previously done, which they appeared to find useful. Participants explained that the sessions had helped them to accept their current functioning and had reduced their frustrations, which is thought to be crucial for adjustment post-stroke (Mukherjee, Levin & Heller, 2006). Nine out of ten of the participants acknowledged changes to their viewpoint following the sessions, suggesting that the sessions may have provided participants with a different way of thinking about what had happened to them and the impact of the stroke on their lives.

Participants also made reference to changes to their behaviour or changes they felt they should make following the sessions; such as being more open, improving communication, contacting friends more or increasing their activity levels. These changes fit with the aims of IPT to improve patients' communication and social support (Stuart & Robertson, 2003). Research also suggests that these changes can be protective in relation to the onset and course of depressed mood post-stroke (Hilari *et al.*, 2010; Salter *et al.*, 2010).

One participant did not find any advantage of the sessions which she linked to her perception that she was no longer depressed during the sessions, although she did comment that the sessions were pleasant.

2.7.1.3 What are the disadvantages of an IPT assessment and formulation for stroke patients experiencing depression?

Two participants acknowledged that the sessions had evoked some negative emotions for them including frustration, anxiety and guilt. Previous research investigating patients' experiences of different psychotherapy models has also found that participants experience negative emotions related to psychotherapy sessions (Elliot, 2008; Mason & Hargreaves, 2001; McManus *et al.*, 2010). Pain *et al.* (2008) found participants experienced negative emotions after receiving a CBT case formulation for psychosis; suggesting that the negative emotions experienced by participants in the current study are perhaps tied in with participating in psychotherapy sessions regardless of the therapeutic model used.

2.7.2 Implications for clinical practice and future research

When designing this study it was hypothesised that IPT should be an appropriate intervention for PSD because a number of the IPT interpersonal problem areas have emerged as themes within the existing post-stroke literature. Guidelines suggest that IPT is an appropriate treatment option when distress can be linked to one of the four interpersonal problem areas (National Institute for Health and Clinical Excellence, 2010). Across the data set participants made reference to their social support and the interpersonal problem areas with nine of the participants acknowledging the link between their low mood and the interpersonal problem areas: grief and loss,

interpersonal disputes and role transitions. By demonstrating that PSD can be linked to interpersonal difficulties, the current study has provided further evidence for the hypothesis that IPT should be an appropriate intervention for PSD.

Participants' experiences of an IPT assessment and formulation also suggest that participants found this model to be acceptable post-stroke. The majority of participants reported benefits of the sessions such as: increasing their awareness of the impact of their stroke on others, reducing their frustrations, and shifting the way they think about what happened and the impact the stroke had on their lives.

All participants at some point in their narratives commented that the assessment and formulation had either not had a "big" impact on them or that things had "slipped back" to the way they were before the session. Participants linked this to being unable to recall details of the sessions and also life events which had occurred following the sessions. However, in the current study participants were only offered an IPT assessment and formulation over two sessions. Participants were not offered a full IPT intervention which would have maintained the focus on the problem area, explored patients' expectations of relationships, used problem solving and other techniques to resolve conflicts, reviewed their progress and introduced relapse prevention techniques (Stuart & Robertson, 2003). Therefore it is not surprising that the majority of participants did not find any significant or lasting impact of the sessions when they did not receive the full intervention. This research was interested in the acceptability of an IPT assessment and formulation post-stroke and we did not set out to investigate if an IPT assessment and formulation would be an effective intervention post-stroke. However, the majority of participants saw a decline in their

depression scores at interview and four participants no longer met the clinical threshold for depression (Table 3). Although we did not quantitatively analyse differences here due to the small sample size, it is possible that the IPT assessment and formulation contributed to the improvement in participants' wellbeing.

Previous research exploring IPT for adolescents found early reductions in depression symptoms at the end of the assessment phase of IPT predicted remission status at the end of therapy (Gunlicks-Stoessel & Mufson, 2011). Therefore participants' experiences of an IPT assessment and formulation should be predictive of their experiences of a full IPT intervention.

Given our findings that participants did appear to find some positive impact of the sessions and the observed decline in depression scores at follow-up it may be interesting to investigate patients' experiences of a full IPT intervention. It is important when evaluating and developing therapeutic interventions that both quantitative and qualitative research methods are used (Mason & Hargreaves, 2001). Therefore a further step would also be to carry out a robust, quantitative analysis of an IPT intervention for PSD to address the methodological limitations of Finkenzeller *et al*'s. (2009) study. The results of the current study also suggest that a shift in patients' viewpoints and acceptance are common following an IPT assessment and formulation; it may therefore be useful for future IPT research to measure the change in these variables alongside mood and behaviour.

The current study is, to our knowledge, the first study looking at patients' experiences of an IPT assessment and formulation for PSD. The results are promising for the acceptability of an IPT model for PSD and add to the evidence

base for the benefits of psychosocial interventions for PSD, where there is currently insufficient evidence for the use of psychosocial interventions for PSD (Cathers *et al.*, unpublished).

Participants in the current study discussed the ‘losses’ they had experienced following their stroke. Within participants’ narratives this was reflected as a grief reaction. These findings further strengthen Stuart and Robertson’s (2003) argument that the grief focus area within IPT can be used to formulate non-bereavement losses.

Previous IPT research with older adults found that participants with cognitive impairment find it more difficult to: engage in psychotherapeutic processes, choose an IPT focus for therapy and recall key events from earlier sessions; therefore cognitive impairment was included as an exclusion criterion in this study (Miller & Reynolds, 2007). However, the results of this study suggest that memory deficits, which were not significant enough to exclude participants from the study, may have limited participants’ ability to engage in the sessions and discuss the sessions during the semi-structured interview. Therefore it may be important for future research investigating IPT for PSD to include modifications to the intervention for co-morbid cognitive impairment like those suggested by Miller and Reynolds (2007). Modifications include integrating the carer into the treatment process in a flexible way to recognize the carers own role transition and resolve any role conflicts between the carer and patient (Miller & Reynolds, 2007). This would be in keeping with the comments of one of the participants who suggested it would be useful if they were not the only person attending the sessions.

2.7.3 Strengths and Limitations of Study

The authors acknowledge that the sample size was relatively small; however the sample was reasonably homogenous, increasing the potential to identify reliable findings within a relatively small sample (Ritchie & Lewis, 2003). All participants had: suffered a stroke within the last four years, were depressed and shared the same therapeutic experience within the same stroke service. While there were some differences within the sample in terms of their age, severity of depression and perceived level of social support, FA allowed researchers to scrutinize these differences in the sample to compare participants' experiences across different ages, depression scores and perceived level of social support to see if these factors accounted for any variations in participants' experiences (Taylor, Franck, Dhawan & Gibson, 2010). There came a point during analysis where little new evidence was obtained from each new participant, this apparent saturation of themes further defends the use of a relatively small sample (Ritchie & Lewis, 2003). Each of the interviews yielded a vast amount of rich data therefore use of a larger sample may have produced an unmanageable amount of data (Ritchie & Lewis, 2003).

The study was a single site study which explored a lived experience of individuals in a routine stroke psychology service and therefore involved patients who would typically present to the service, increasing the clinical validity of the study. None of the participants had previously taken part in an IPT intervention and therefore had no fixed ideas about what they were going into.

While the therapist was not formally accredited in practising IPT, the sessions followed a structured protocol and were rated for IPT quality by an accredited IPT

therapist. However, the session protocol and formulation template were designed by the authors and therefore are open to criticism. The assessment and formulation protocol did not include all the components of a typical IPT assessment such as contracting the treatment process. While this is a limitation of the study, the authors felt providing these components would not have been appropriate as a full IPT intervention was not offered or provided. Whilst it would have been useful to have evaluated patients' experiences of a full IPT intervention, this was not possible with current clinical resources and time constraints.

The authors are aware of the potential bias of the researcher being associated with the Psychology service as part of her work component. Although participants were reassured that the interviews were confidential, participants may have felt obliged to portray their experience positively. Participants often apologised when passing a comment that may have been perceived as negative about the sessions.

The interviews were conducted retrospectively to allow participants time to process the formulation although this introduced memory biases, social factors and allowed for life events to occur after the sessions which may have impacted on participants' mood (Williams *et al.*, 2011).

2.8 Conclusions

Overall the results demonstrated that PSD can be linked to at least three of the four IPT interpersonal problem areas, providing further evidence for the initial hypothesis that IPT should be an appropriate intervention for PSD. The results highlighted that participants found an IPT assessment and formulation of their low mood post-stroke to be acceptable. Participants suggested benefits of the IPT assessment and

formulation such as: altering their point of view, recognising the impact of their stroke on others, increasing acceptance of impaired functioning, reducing frustration, increasing positive feelings and leading to improvements in their social support. Although participants recognised that the lasting advantages in terms of their mood were limited, this reflected the time-limited nature of the intervention participants received. IPT may therefore be a suitable intervention for PSD and further robust, quantitative research is justifiable.

2.9 Acknowledgements:

We would like to thank all the participants for taking part in the study. We would also like to thank the Stroke Liaison Nurses who were involved with the recruitment phase of this study. Thank you to Dr John Higgon, Consultant Clinical Neuropsychologist for his input.

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2.11 Empirical Study Journal Article Appendix

Final Thematic Framework for Qualitative Analysis Version six 23rd January 2014

1 Acknowledging life events	5 Impact of the sessions
1.1 Describing life history	5.1 Lack of impact/ slipping back
1.2 Life events since IPT sessions	5.2 Acceptance of current situation
	5.3 More understanding/ less frustrated
2 Difficulties linked to stroke	5.4 Recognising impact on others
2.1 Rehabilitation/ changes in functioning	5.5 Increasing social activities
2.2 Fatigue	5.6 Improvements to social support
2.3 Cognitive impairment	5.7 Recognising need to make changes
2.4 Stroke experience	5.8 Thought provoking
2.5 Medication	5.9 Clarification/ Reinforced/ confirmation/ Realisation/highlighting
2.6 Mood	5.10 Making connections
	5.11 Accessing deeper feelings
	5.12 Being left with positive feelings (uplifted/ relaxed/ feeling free/ feeling lucky)
Structure of Assessment	5.13 Acknowledging negative feelings (guilt/ embarrassment)
3 process	5.14 Encouraging others to take part
3.1 Material Covered/ layout of sessions	5.15 Need to be open and honest
3.2 The layout of the formulation	
3.3 Comparing IPT to other models	
3.4 Looking at social support/ relationships	
3.5 Looking at role	6 Fears
3.6 Looking at loss	6.1 Anxiety
	6.2 Possibility of future strokes
4 Therapist Qualities	
4.1 Therapist Qualities	
4.2 The accuracy of the formulation	
4.3 Therapist being impartial/ talking in confidence	

3. Additional Methodology

An additional methods chapter has been included to convey details of the methodology which could not be outlined within the confines of the journal article (chapter 2).

3.1 Post-Stroke Depression

In the DSM-IV-TR, post-stroke depression (PSD) is categorized as a ‘Mood Disorder Due to a General Medical Condition’ (p.346); which specifies that the mood disturbance is a direct result of the stroke (American Psychiatric Association, 2000). The researcher was aware that some participants may have experienced pre-stroke depression. It was therefore important to determine if participants’ current difficulties were related to their stroke or a pre-morbid difficulty. The researcher decided not to exclude all participants who had experienced pre-stroke depression as it was felt this would not be representative of patients who ordinarily present to the stroke Psychology service with low mood. A discussion was held with the Stroke Liaison Nurses (SLNs) regarding each potential participant to ensure that their current difficulties were related to their stroke. It was decided that if it became apparent that a participant’s difficulties were not related to their experience of a stroke, then their data would not be included in analysis. However, for all participants who consented to take part in the study their distress appeared to be primarily related to their stroke.

3.2 Measures used to describe the sample

Permission to use all four measures was obtained from the copyright holders.

3.2.1 The Hospital Anxiety and Depression Scale (HADS)

The HADS is a measure of anxiety and depression specifically developed for patients with somatic comorbidity (Zigmond & Snaith 1983). The scale consists of two 7-item subscales: an anxiety subscale (HADS-A) and a depression subscale (HADS-D) (Bjelland *et al.*, 2002). For each subscale the total score is out of 21, higher scores are indicative of greater levels of anxiety and depression (Flint & Rifat, 2002). In Zigmond and Snaith's (1983) original study they suggested a clinical cut off score of eight or above on either subscale; this has been found to be optimal cut off in stroke patients (Aben *et al.*, 2002). Aben *et al.* (2002) found the HADS to have high sensitivity and specificity in a stroke population. The current study used the HADS-D as part of the inclusion criteria for the study. The study administered the full HADS to describe the sample in terms of anxiety and depression levels. Participants completed the HADS prior to the interpersonal psychotherapy (IPT) sessions and after the IPT sessions, during the semi-structured interview.

3.2.2 The Fatigue Assessment Scale (FAS)

The FAS (Michielsen *et al.*, 2003) is a 10-item measure of fatigue which has been found to have good face validity, feasibility, test-retest reliability and construct validity in post-stroke patients (Mead *et al.*, 2007; Smith *et al.*, 2008). Although Mead *et al.* (2007) found the internal consistency for the scale to be low (Cronbach's $\alpha = 0.58$ and 0.62) they suggest that this may be because the scale measures different facets of fatigue. Participants completed the FAS prior to the IPT sessions.

3.2.3 The Multidimensional Scale of Perceived Social Support (MSPSS)

The MSPSS (Zimet *et al.*, 1988) is a 12-item self-report scale which measures the perceived availability and satisfaction of support from friends, family and a special person (Frasure-Smith *et al.*, 2000). The scale has good internal validity and test-retest reliability and moderate construct validity (Zimet *et al.*, 1988). The scale has been used previously in a stroke population (Frasure-Smith *et al.* 2000) although its validity and reliability have not been formally tested in this population. Participants completed the MSPSS prior to the IPT sessions.

3.2.4 The Montreal Cognitive Assessment (MoCA)

Previous IPT research with older adults found that participants with cognitive impairment find it more difficult to: engage in psychotherapeutic processes, choose an IPT focus for therapy and recall key events from earlier sessions; therefore cognitive impairment was included as an exclusion criterion in the current study (Miller & Reynolds, 2007). The MoCA (Nasreddine *et al.*, 2005) was administered to detect mild forms of cognitive impairment. The MoCA evaluates eight cognitive domains: memory, attention, language, executive functioning, working memory, visuospatial ability, concentration and orientation (Nasreddine *et al.*, 2005). Within an older adult population and a population with dementia, the MoCA has demonstrated good internal consistency and has been found to have good sensitivity and specificity for mild cognitive impairments in a post-stroke population (Nasreddine *et al.*, 2005; Pendlebury *et al.*, 2012). The MoCA is scored out of a total of 30; scores of 26 or lower were originally thought to indicate the presence of cognitive impairment (Pendlebury *et al.*, 2012). However, Rossetti *et al.* (2011)

argue that when looking at larger, more diverse population-based samples, this cut off is too high. Given the high failure rate across an older adult population on some of the items, an impairment cut off score of below 23 is thought to be more appropriate (Rossetti *et al.*, 2011).

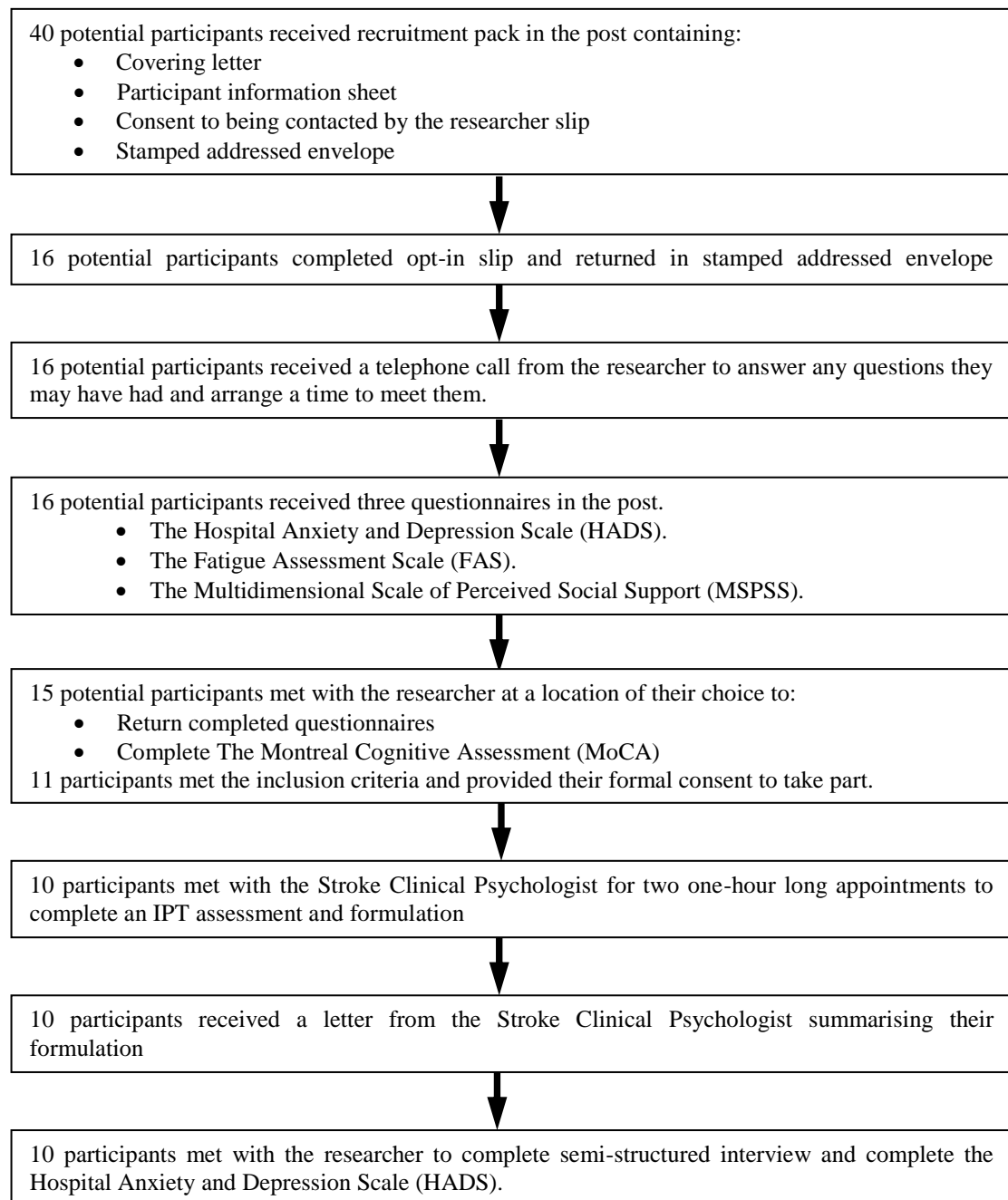


Figure 1: Participant flow through the different stages of the procedure

3.3 Data Analysis

The study followed the five dynamic stages of framework analysis (FA) described by Ritchie and Spencer (1994).

3.3.1 Familiarisation

This stage began during the transcription process where the researcher listened to the audio recordings from all the participants' interviews and transcribed them into written verbatim. The researcher then read and re-read all the interview transcripts to become familiar with them (Ritchie & Lewis, 2003). During the later stages of familiarisation the researcher noted recurring ideas and themes within participants' narratives. Themes were described using terms which matched the language used in participants' narratives (Ritchie & Lewis, 2003).

3.3.2 Identifying a thematic framework.

Each of these recurring themes within participants' narratives was then written on separate pieces of paper. This allowed the researcher to group similar themes together to produce a hierarchy of main themes with a series of linked subtopics. Sorting and grouping themes in this way creates what is known as a thematic framework (Ritchie & Lewis, 2003; Srivastava & Thomson, 2009). This thematic framework was then applied to the raw data set. The thematic framework was continually refined during this process creating six versions of the index.

3.3.3 Indexing

The final version of the thematic framework (version 6) (see Appendix A in chapter 2) was then applied to the full raw data set in a process known as indexing. Each sentence from participants' narratives were considered in turn and coded using the thematic framework to show which themes were referred to in that particular sentence (Ritchie & Lewis, 2003; Srivastava & Thomson, 2009).

3.3.4 Charting

Participants' quotes which had been indexed using the thematic framework were then extracted and sorted by theme and participant into a thematic chart (Ritchie & Lewis, 2003). Computerised spreadsheet software was used to sort data in this way. This process allowed all similar content to be located together and allowed the researcher to spend time unpacking the detail and making distinctions and connections within and between the themes (Ritchie & Lewis, 2003; Srivastava & Thomson, 2009). The researcher spent time summarising and synthesising the extracted quotes, retaining participants' language as much as possible.

3.3.5 Mapping and interpretation.

The thematic charts were used to develop associations and patterns within themes. The researcher spent time interpreting and seeking wider application for the identified themes (Smith & Frith, 2011).

3.4 Ensuring Quality in Qualitative Research

Yardley (2000; 2008) proposed the following principles which could be used to assess the quality of qualitative research methods.

3.4.1 Sensitivity to context

Qualitative research must be sensitive to the relevant literature and previous empirical work (Yardley, 2000). Therefore a comprehensive review of the existing literature was carried out early in this project to help inform the aims and methodology of the study which addressed the gaps in our current understanding of the use of IPT for PSD (see Chapters 1 & 2).

Yardley (2000; 2008) also indicates the importance of researchers being aware of the socio-cultural setting of the study. The researcher was aware that there may have been a power imbalance in the relationship between the researcher and participants and was therefore mindful of this in the language they used (Smith *et al.*, 2009). Participants chose the venue for the IPT sessions and the semi-structured interview to allow them to feel comfortable in their surroundings. The researcher was also aware that their association with the Psychology Service as part of her work component may have created a potential bias (Yardley, 2008). Participants may therefore have been reluctant to discuss their honest opinions of the sessions if they were negative. To address this issue, participants were clearly informed from the outset that the interviews were confidential.

3.4.2 Commitment and Rigour

Commitment refers to sustained engagement with the study, evolving skills in the methods used and immersion in the data (Yardley, 2000). The researcher spent a large amount of time reviewing the existing literature base and reading around FA methodologies. Commitment was also demonstrated in the level of attention paid to individual participants during the study. The researcher transcribed all participants' interviews and checked these against the audio recordings for accuracy. A substantial amount of time was spent by the researcher immersing themselves in data to familiarise themselves with it.

Rigour denotes the completeness of the data (Yardley, 2000). Although the inclusion and exclusion criteria adopted in this study aimed to maintain a relatively homogenous sample, there were some differences within the sample in terms of their age, severity of depression and time since stroke occurred which suggests that a range of perspectives were sampled (Yardley, 2008). FA allowed researchers to scrutinise these differences in the sample to see if these factors accounted for any variations in participants' experiences (Taylor *et al.*, 2010). A second researcher was consulted frequently throughout analysis to discuss emerging themes, potential index refinement and ways to display the data (Yardley, 2008). The researcher was mindful not to impose their categorisations on the data and remained open to other explanations (Yardley, 2008). The researcher also noted disconfirming instances which did not fit with the themes identified (Mays & Pope, 2000; Yardley, 2008).

3.4.3 Transparency and Coherence

Coherence refers to the ‘fit’ between the theoretical background of the study, the methods used and the interpretation of the data (Yardley, 2000; 2008). The data analysis method used was determined by the study’s aims (as detailed in the empirical study journal article in chapter 2).

Transparency refers to the clear detailing of every stage of the methodology (Yardley, 2000). A step-by-step account of the methods used along with a rationale for these methods has been included. The researcher has included copies of the IPT assessment and formulation session protocol and semi-structured interview schedule in Appendices 8 and 9. The formulation template used was included as a figure (Figure 1) in chapter 2. The final version of the thematic framework, examples of the process of arriving at a theme and an example of a thematic chart have been included in the empirical study journal article Appendix (chapter 2) and Appendices 10 and 11 to demonstrate the analytic interpretations of the data. FA allows analysts to move between the dynamic stages, leading to transparency in the themes (Ritchie & Lewis, 2003). The themes identified also closely retained the language used by participants, creating further transparency in analysis (Ritchie & Lewis, 2003).

3.4.4 Impact and Importance

Impact and importance refers to the contributions that the study makes to existing theoretical knowledge or clinical practice (Yardley, 2000). The impact and importance of this project is clearly reported in the empirical study journal article (chapter 2).

3.5 Ethical Considerations

Ethical approval was given by the West of Scotland Research Ethics Service and the local Research and Development Department (see Appendices 5 & 6). Approval was also given by the local Caldicott Guardian (see Appendix 7). The study followed the British Psychological Society's Code of Ethics and Conduct (2009) and Code of Human Research Ethics (2010).

3.5.1 Recruitment

The Stroke Liaison Nurses (SLNs) and the Clinical Psychologist working in the area of stroke were part of the clinical team and were asked to contact potential participants on behalf of the researcher. The SLNs routinely follow-up all stroke patients in the region; each patient is allocated a SLN who visits them up to five times during the first 12 months post-stroke. The SLNs were asked to identify participants for the current study from the admissions database, using the inclusion and exclusion criteria. As the SLNs have regular contact with patients during the first year post-stroke, they are familiar with patients' situations and were therefore able to identify which patients on their database would likely meet the inclusion and exclusion criteria. The SLNs therefore only contacted potentially eligible patients, reducing the number of patients who were contacted but did not meet the inclusion criteria to take part in the study. The SLNs and Clinical Psychologist were given sealed recruitment packs containing a letter inviting potential participants to take part, a participant information sheet, an opt-in slip and a stamped addressed envelope. The SLNs and Clinical Psychologist were asked to attach the relevant

address label to the recruitment pack and place the pack in the post on behalf of the researcher.

As the study recruited patients up to four years post-stroke it was possible that patients' circumstances may have changed since their last contact with the SLN. The SLNs therefore checked that patients were still alive on the Multi-Disciplinary Information System (MiDIS) prior to contacting inactive patients from their database. As patients are familiar with the SLNs it was important that they did not feel coerced into taking part in the research (Dench *et al.*, 2004). Potential participants were clearly informed that deciding not to take part in the study would not impact on their current care. Potential participants were invited to take their time considering the study and to discuss it with others.

The SLNs do not routinely use standardised measures for depression and cognitive impairment for all stroke patients. The SLNs could therefore not be certain of potential participants' scores on the HADS-D or MoCA. It was therefore clearly explained in the participant information sheet and the invitation letter that participants were not approached specifically because it was thought that they were experiencing depression but rather that there was a possibility that they may be. It was also stated that should they opt-in to the study they may not be asked to take part in the study as they may not meet the relevant criteria. The four stroke patients who did not meet the inclusion criteria at assessment were offered the opportunity to receive psychological input under the current Stroke Psychology Service's provisions which provides interventions using cognitive-behavioural therapy (CBT), behavioural activation, problem solving and psychoeducation.

3.5.2 Follow-up

An identified ethical consideration was that a full 12-16 week IPT intervention was not offered to participants, despite their participation in an IPT orientated assessment and formulation. All participants were clearly informed that IPT was not currently offered by the Stroke Psychology Service and that they would only be receiving two appointments and a follow-up interview. All participants were offered the opportunity to receive further psychological input under the current Stroke Psychology Service's provisions. A structured protocol was used (see Appendix 12) for referring participants on for further input following the semi-structured interview. Two participants received one additional session under the current service provisions following the termination of the study, in both cases the participants' General Practitioners (GPs) were informed in writing.

3.5.3 Patient distress

Due to the nature of the IPT assessment and formulation sessions it was possible that participants may have reported high levels of distress, expressed suicidal ideation or disclosed a risk of harm to themselves or others. During the recruitment process all participants were informed that should any of these concerns be identified then both the researcher and the Clinical Psychologist had an ethical duty to act on this information and inform their GP. Participants were informed that should this happen then they would also be referred to the Stroke Psychology Service for further input under the current service provisions (see Appendix 12).

3.5.4 Confidentiality

The researcher did not have access to any patients' details prior to the potential participant opting-in to the study. Potential participants were informed on the participant information sheet that by choosing to opt-in to the study they were providing consent for the researcher to access their name and contact details. During the formal consent process, informed consent was gained for the researcher to access participants' personal records if this was needed as part of the study.

Personal information was stored in line with the local NHS' Confidentiality Policy and the Data Protection Act 1998. The audio recordings of the IPT sessions and semi-structured interview were downloaded onto CDs. Each CD was labelled with a unique number to identify the participant and session. These CDs were stored in locked filing cabinets within the local Psychology department. Once downloaded onto a CD, all audio recordings were deleted from the digital recording device. All CDs will be destroyed as confidential waste in keeping with the local NHS' Confidentiality Policy once the write up of this study is completed.

The audio recordings were transcribed; to ensure anonymity all participant identifiable information was removed from the transcripts. The transcripts were stored on the local NHS' server as password protected files. Each transcript was labelled with the participant's unique number. No personal information was stored with these files. These transcriptions will be securely archived within the University of Edinburgh and will be accessible to the researcher and study supervisor for purposes such as publication, addressing queries from other academics or clinicians in relation to the project. This unidentifiable data will be reviewed after 10 years to

determine whether it should continue to be retained or be securely deleted. If retained, this data will be reviewed every five years.

All participants were clearly informed that the results of the study would be written up in a way that does not identify individual participants.

3.5.5 Cognitive impairment and capacity to consent

Mild cognitive impairment is common post-stroke (Pendlebury *et al.*, 2010). Patients whose cognitive functioning fell below the cut-off score of 23 on the MoCA were excluded from the study to ensure that all participants had the cognitive abilities necessary to take part in the study. It was necessary that all participants had the ability to recall the content of sessions and recent events, were able to process the information provided with the formulation and retain this information for the interview (Miller & Reynolds, 2007).

Cognitive impairment may also impact on participants' capacity to consent. Therefore the capacity to consent was assessed for all potential participants. To assess capacity to consent the researcher clearly explained the purpose of the study and what participation would involve. Participants were then asked to explain this back to the researcher to check their understanding of this.

3.5.6 Possible risk to the researcher

There were possible risks related to the researcher and the Clinical Psychologist conducting appointments in participants' homes. Therefore the local NHS' Lone Worker Policy was followed.

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